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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–3989; Directorate Identifier 2014–NM–220–AD; Amendment 39–18629; AD 2016–17–16]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. This AD was prompted by in-service reports of passenger door tensator spring failures, and qualification testing indicating that non-conforming tensator springs could be susceptible to failure prior to reaching their safe-life limit. This AD requires revising the maintenance or inspection program to incorporate certain temporary revisions, and replacing the passenger door tensator springs with new springs. We are issuing this AD to prevent tensator spring failure, resulting in the inability to open the main passenger door, which could impede evacuation in the event of an emergency.

DATES: This AD is effective October 5, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 5, 2016.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3989.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3989; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Fabio Buttitta, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7303; fax: 516–794–5531: email: *Fabio.Buttitta@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. The NPRM published in the **Federal Register** on March 4, 2016 (81 FR 11471) (''the NPRM'').

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2014–39, dated November 4, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states:

> Following the issuance of [Canadian] AD CF–2010–14, additional qualification testing of the passenger door tensator spring, Part Number (P/N) GS321–0580–1, determined that the tensator springs could be susceptible to failure prior to reaching the life limit mandated by [Canadian] AD CF–2010–14.
>
> In addition, there have been in-service reports of passenger door tensator spring failures. Investigation determined that the material used to manufacture the tensator springs [was] improperly heat treated.
>
> The passenger door assembly is installed with four tensator springs that assist the door actuator in opening and closing the door. In-service experience has shown that a failed tensator spring could uncoil and foul up the rotating tensator spools, resulting in the inability to open the main passenger door. The inability to open the main passenger door could impede evacuation in the event of an emergency.
>
> This [Canadian] AD mandates the revision to the approved maintenance schedule to reduce the repetitive discard task interval and mandates the replacement of non-conforming tensator springs.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3989.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Include Service Information

Bombardier, Inc. requested that we revise the Related Service Information under 1 CFR part 51 section and paragraph (g) of the proposed AD to include Temporary Revision (TR) 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks.

We agree to include TR 5–2–10, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks, as requested by the commenter. Our intent is to correspond with TCCA Canadian AD CF–2014–39, dated November 4, 2014, which includes TR 5–2–9, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight

Deck—Time Limits/Maintenance Checks. TR 5–2–10, dated June 4, 2014, supersedes TR 5–2–9, dated September 9, 2014. We have included TR 5–2–10, dated June 4, 2014, in paragraph (g)(2) of this AD and redesignated subsequent paragraph identifiers accordingly. We have also included that same TR in the Related Service Information under 1 CFR part 51 section of this final rule. Since the NPRM inadvertently did not include a TR to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks, we must make this change to avoid operators needing to ask for approval of an alternative method of compliance (AMOC) to use a TR in order to comply with the revision required by paragraph (g) of this AD.

In addition, we have revised paragraph (g) of this AD to refer to Task Number 52–11–41–101 because some TRs include multiple tasks. This AD specifically addresses the passenger door tensator spring, part number GS321–0580–1, and the task number in the TRs for that component is 52–11–41–101.

Request To Correct Typographical Error

Bombardier, Inc. requested that we revise paragraph (g)(2) of the proposed AD to read "Model BD–700–1A10 airplanes," instead of "Model BD–700–1A11 airplanes."

We agree. This was a typographical error, and has been corrected in paragraph (g)(3) of this AD (paragraph (g)(2) of the proposed AD).

Request To Revise Compliance Time

NetJets requested that we revise the proposed AD so that the threshold for the initial spring replacement is based on the AD effective date, and not the TR revision date. NetJets explained that paragraph (g) of the proposed AD specifies that the compliance time for the initial replacement is per the TRs listed in paragraphs (g)(1) through (g)(4) of the proposed AD, or within 30 days after the AD effective date, whichever occurs later. NetJets explained further that the TRs base the threshold from the TR revision date of "Jun 04/2014," and that by the time the final rule is released, the threshold in the TR will have been exceeded by approximately 2 years. NetJets argued that, therefore, the final rule will effectively mandate a 30-day threshold, which is an undue burden without technical justification.

We do not agree with the request to revise the compliance time in this AD. The compliance time in this AD corresponds with the compliance time in Canadian AD CF–2014–39, dated November 4, 2014. In addition, the commenter did not provide any data to substantiate that extending the compliance time would provide an acceptable level of safety. After considering all the available information, we have determined that the compliance time, as proposed, represents an appropriate interval of time in which the required actions can be performed in a timely manner within the affected fleet, while still maintaining an adequate level of safety. Under the provisions of paragraph (k)(1) of this AD, however, we may consider requests for adjustments to the compliance time if data are submitted to substantiate that such an adjustment would provide an acceptable level of safety. We have made no changes to this AD in this regard.

Request To Allow for Later-Approved Revisions of Service Information

NetJets requested that we revise the NPRM to add provisions to allow later FAA-approved revisions to the time limits/maintenance checks manuals (TLMCM), so that an approval of an AMOC will not be required to incorporate the currently published TLMCM revision and future revisions. NetJets explained that the TRs specified in paragraphs (g)(1) through (g)(4) of the proposed AD have been incorporated in revisions to the listed TLMCMs.

We find that clarification is necessary. Once operators have incorporated the task in the TR into their maintenance or inspection program, the task cannot be changed without approval of an AMOC. However, once the task in the TR is incorporated into the TLMCM, operators that use the TLMCM are still in compliance because the task has not changed. If a future revision of the TLMCM changes the task, then an AMOC would be needed to use the revised task.

We have revised paragraph (g) of this AD to clarify that the revision may be done by inserting copies of the TRs identified in paragraphs (g)(1) through (g)(5) of this AD into the applicable TLMCM. When the information in a TR has been included in general revisions of the applicable TLMCM, the general revisions may be inserted in the TLMCM, and the TR may be removed.

Request for Clarification of the Necessity for a Life Limit Requirement

NetJets requested that we clarify the necessity for the life limit requirement in paragraph (i) of the proposed AD. NetJets stated that paragraph (i) of the proposed AD requires a threshold of ". . . but not exceeding the applicable life limit of the passenger tensator spring . . ." without identifying the referenced life limit, and noted that the listed service information does not include a life limit requirement.

We agree to clarify the requirement specified in paragraph (i) of this AD and the necessity for that requirement. The passenger door assembly is installed with four tensator springs that assist the door actuator in opening and closing the door. In-service experience has shown that a failed tensator spring could uncoil and foul up the rotating tensator spools, resulting in the inability to open the main passenger door. The inability to open the main passenger door could impede evacuation in the event of an emergency. The actions required by this AD are necessary to address the identified unsafe condition.

Paragraph (g) of this AD mandates the revision to the approved maintenance schedule by incorporating TRs to reduce the repetitive discard task interval. Paragraph (i) of this AD mandates, for certain airplanes, the replacement of non-conforming tensator springs within 15 months after the effective date of this AD, but not exceeding the applicable life limit of 1,500 landings for the component as listed in the applicable TRs identified in paragraph (g) of this AD. The replacement is necessary to ensure the airplanes identified in section 1.A., "Effectivity," of Bombardier Global 5000 Service Bulletin 700–1A11–52–023, dated October 4, 2013; or Bombardier Global Express/Global Express XRS Service Bulletin 700–52–046, dated October 4, 2013, replace the tensator springs within 15 months, as specified in that service information, but not later than the new life limit. We have revised paragraph (i) of this AD to refer to the TRs in paragraph (g) of this AD for the life limit.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed the following Bombardier, Inc. service information:

- Bombardier Global 5000 Service Bulletin 700–1A11–52–023, dated October 4, 2013.
- Bombardier Global Express/Global Express XRS Service Bulletin 700–52–046, dated October 4, 2013.
- TR 5–2–7, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express XRS BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).
- TR 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks (for Model BD–700–1A11 airplanes).
- TR 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 6000 GL 6000 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).
- TR 5–2–13, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A11 airplanes).
- TR 5–2–44, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).

The service information describes procedures for replacing passenger door tensator springs with new springs. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 60 airplanes of U.S. registry.

We also estimate that it would take about 40 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $204,000, or $3,400 per product.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–17–16 Bombardier, Inc.: Amendment 39–18629. Docket No. FAA–2016–3989; Directorate Identifier 2014–NM–220–AD.

(a) Effective Date

This AD is effective October 5, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9002 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by in-service reports of passenger door tensator spring failures, and qualification testing indicating that non-conforming tensator springs could be susceptible to failure prior to reaching their safe-life limit. We are issuing this AD to prevent tensator spring failure, resulting in the inability to open the main passenger door, which could impede evacuation in the event of an emergency.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance or Inspection Program Revision

Within 30 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate task number 52–11–41–101 as specified in the Temporary Revisions (TRs) identified in paragraphs (g)(1) through (g)(5) of this AD. The compliance time for doing the initial replacement of the passenger door tensator springs with new springs is at the times specified in the applicable TR specified in paragraphs (g)(1) through (g)(5) of this AD, or within 30 days after the effective date of this AD, whichever occurs later. The revision required by this paragraph may be done by inserting copies of the TRs identified in paragraphs (g)(1) through (g)(5) of this AD into the applicable Time Limits/Maintenance Checks manual. When the information in a TR has been included in general revisions of the applicable Time Limits/Maintenance Checks manual, the general revisions may be inserted in the Time Limits/Maintenance Checks manual, and the TR may be removed.

(1) TR 5–2–7, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express XRS BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).

(2) TR 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks (for Model BD–700–1A11 airplanes).

(3) TR 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 6000 GL 6000 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).

(4) TR 5–2–13, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A11 airplanes).

(5) TR 5–2–44, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express BD–700 Time Limits/Maintenance Checks (for Model BD–700–1A10 airplanes).

(h) No Alternative Actions and Intervals

After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.*, inspections) and intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (k)(1) of this AD.

(i) Replacement

For airplanes identified in section 1.A., "Effectivity," of Bombardier Global 5000 Service Bulletin 700–1A11–52–023, dated October 4, 2013; or Bombardier Global Express/Global Express XRS Service Bulletin 700–52–046, dated October 4, 2013; except as provided by paragraph (j)(1) or (j)(2) of this AD: Within 15 months after the effective date of this AD, but not exceeding the applicable life limit of the passenger tensator spring identified in the applicable TR specified in paragraphs (g)(1) through (g)(5) of this AD, replace the passenger door tensator springs having part number (P/N) GS321–0580–1, with new springs, in accordance with the Accomplishment Instructions of Bombardier Global 5000 Service Bulletin 700–1A11–52–023, dated October 4, 2013; or Bombardier Global Express/Global Express XRS Service Bulletin 700–52–046, dated October 4, 2013; as applicable.

(j) Acceptable Alternative Actions for Paragraph (i) of This AD

(1) For airplanes having serial numbers (S/N) 9278 through 9360 inclusive: Replacement of the passenger door tensator springs having P/N GS321–0580–1 with new springs before the effective date of this AD is acceptable for compliance with the requirements of paragraph (i) of this AD. Refer to the task specified in the applicable TRs identified in paragraphs (g)(1) through (g)(5) of this AD for subsequent spring replacements.

(2) For airplanes with serial numbers other than those identified in paragraph (j)(1) of this AD: Accomplishment after the effective date of this AD of the "Time Limits/Maintenance Checks" discard task identified in the applicable service information specified in paragraphs (g)(1) through (g)(5) of this AD is acceptable for compliance with the requirements of paragraph (i) of this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the New York ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2014–39, dated November 4, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3989.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Temporary Revision 5–2–7, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express XRS BD–700 Time Limits/Maintenance Checks.

(ii) Temporary Revision 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 GL 5000 Featuring Global Vision Flight Deck—Time Limits/Maintenance Checks.

(iii) Temporary Revision 5–2–10, dated September 9, 2014, to Part 2, Section 5–10–11, of Bombardier Global 6000 GL 6000 Time Limits/Maintenance Checks.

(iv) Temporary Revision 5–2–13, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global 5000 BD–700 Time Limits/Maintenance Checks.

(v) Temporary Revision 5–2–44, dated June 4, 2014, to Part 2, Section 5–10–11, of Bombardier Global Express BD–700 Time Limits/Maintenance Checks.

(vi) Bombardier Global Express/Global Express XRS Service Bulletin 700–52–046, dated October 4, 2013.

(vii) Bombardier Global 5000 Service Bulletin 700–1A11–52–023, dated October 4, 2013.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20693 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–8133; Directorate Identifier 2015–NM–101–AD; Amendment 39–18631; AD 2016–18–01]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. This AD was prompted by reports of heavy corrosion and chrome damage on the forward and aft trunnion pin assemblies of the right and left main landing gears (MLGs). This AD requires repetitive lubrication of the forward and aft trunnion pin assemblies of the right and left MLGs; repetitive inspections of these assemblies for corrosion and chrome damage, and related investigative and corrective actions if necessary; and installation of new or modified trunnion pin assembly components, which will terminate the repetitive lubrication and repetitive inspections. We are issuing this AD to detect and correct heavy corrosion and chrome damage on the forward and aft trunnion pin assemblies of the right and left MLGs, which could result in cracking of these assemblies and collapse of the MLGs.

DATES: This AD is effective October 5, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 5, 2016.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8133.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8133; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6450; fax: 425–917–6590; email: *alan.pohl@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. The NPRM published in the **Federal Register** on December 31, 2015 (80 FR 81795) (“the NPRM”). The NPRM was prompted by reports of heavy corrosion and chrome damage on the forward and aft trunnion pin assemblies of the right and left MLGs. The NPRM proposed to require repetitive lubrication of the forward and aft trunnion pin assemblies of the right and left MLGs; repetitive inspections of these assemblies for corrosion and chrome damage, and related investigative and corrective actions if necessary; and installation of new or modified trunnion pin assembly components, which would terminate the repetitive lubrication and repetitive inspections. We are issuing this AD to detect and correct heavy corrosion and chrome damage on the forward and aft trunnion pin assemblies of the right and left MLGs, which could result in cracking of these assemblies and collapse of the MLGs.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

Boeing stated that it concurs with the contents of the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing Supplemental Type Certificate (STC) ST00830SE does not affect the accomplishment of the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) and added new paragraph (c)(2) in this AD to state that installation of STC ST00830SE does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST00830SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request for Clarification of Requirements

Delta Airlines (DAL) requested an explanation of how the requirements are different between AD 2014–08–11, Amendment 39–17835 (79 FR 23903, April 29, 2014) (“AD 2014–08–11”) and the NPRM. DAL noted that the requirements of AD 2014–08–11 include an inspection for discrepancies of the transition radius of the MLG forward trunnion pins, and corrective actions if necessary. DAL elaborated that this inspection is for finish damage (scrapes through primer), signs of corrosion, pitting, and scratches in the base metal of that area. DAL pointed out that the NPRM requires a general visual inspection of the MLG forward trunnion pin assembly for signs of corrosion or chrome plating damage, and if either condition is found, a detailed inspection of the forward trunnion pin assembly is required. DAL mentioned that the detailed inspection requires verification that a new seal and retainer configuration is installed, and if the overhaul limits exceed what is specified in the component maintenance manual, replacement of the forward trunnion pin assembly is necessary. DAL reasoned that the forward trunnion pin inspections required by AD 2014–08–11 should be superseded by the proposed forward trunnion pin inspections in the NPRM. DAL stated that the detailed inspection proposed in the NPRM has additional corrective actions if any loose or missing chrome plating is found, beyond what is required in AD 2014–08–11. DAL also conveyed that the inspections for signs of corrosion are the same in the NPRM and AD 2014–08–11.

We agree to provide clarification regarding how the requirements are different between the requirements in the proposed AD and the requirements mandated by AD 2014–08–11. The applicability of the proposed AD includes certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, line numbers 1 through 3526 inclusive. The applicability of AD 2014–08–11 includes certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, line numbers 1423 through 3526 inclusive. Although certain airplane line numbers are included in the applicability of both the proposed AD and AD 2014–08–11, the issues addressed by the NPRM and AD 2014–08–11 are not the same. Furthermore, the inspection instructions in the service information required for accomplishing the actions in the proposed AD are different from the inspection instructions in the service information required by AD 2014–08–11. The inspections in the proposed AD focus on chrome damage and corrosion on the shank of the forward trunnion pins, and the inspections required by AD 2014–08–11 focus on finish scratches and corrosion in the transition radius of the forward trunnion pins. We have not changed this AD regarding this issue.

In addition, we note that the service information required to do the actions required by AD 2014–08–11 (which cites Boeing Special Attention Service Bulletin 737–32–1402, Revision 1, dated February 7, 2013), includes a recommendation by Boeing that operators accomplish the specified actions concurrently with the actions specified in Boeing Special Attention Service Bulletin 737–32–1448 (Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, is the appropriate source of service information for accomplishing the actions required by this AD).

Likewise, Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, includes a recommendation by Boeing that operators accomplish the specified actions concurrently with the actions specified in Boeing Special Attention Service Bulletin 737–32–1402.

Request for Clarification of Lube Fittings Location

DAL requested clarification regarding the location of the lube fittings for the forward and aft MLG trunnion pin assemblies in paragraph (g) of the NPRM. DAL commented that the NPRM stated to do the repetitive lubrication in accordance with Work Package 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. DAL noted that Work Package 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, refers to section 12–21–11 of the Boeing 737–600/700/800/900 Aircraft Maintenance Manual (AMM) as an accepted procedure for the repetitive lubrication of the MLG trunnion pin assemblies. DAL stated that section 12–21–11 of the AMM specifically identifies the locations of the trunnion bearing housing and the aft trunnion bearing, but does not specifically identify the locations of the two lube fittings for the forward and aft trunnion pins.

We agree with the commenter that the two lube fittings for the forward and aft trunnion pins are not specifically mentioned in section 12–21–11 of the Boeing 737–600/700/800/900 AMM. These locations are identified as Item [6], "Outer Cylinder," on page 307 of the AMM. However, there are only three lube fittings associated with Item [6], so it is possible to determine which two fittings are to be used for lubricating the forward and aft trunnion pins. We consulted with Boeing and confirmed that the two lube fittings are located on the bottom of the outer cylinder trunnion, directly under the pins. We have not changed this AD regarding this issue.

Request for Clarification of Corrective Actions in Paragraph (h) of the Proposed AD

DAL requested clarification of certain corrective actions in paragraph (h) of the proposed AD. DAL asked if an operator can replace an affected trunnion pin assembly instead of overhauling it. DAL pointed out that neither the NPRM nor Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, specify the part number of the replacement trunnion pin assembly. DAL asked if an operator can replace an affected pin assembly with any properly approved pin assembly using the Boeing 737 Aircraft Illustrated Parts Catalog, Boeing Drawing 161A0002, "Boeing Model 737–NG Main Landing Gear Component Interchangeability List," or a similar document.

We agree with the commenter's request for clarification. Operators may elect to replace a trunnion pin assembly with a serviceable unit in lieu of performing an overhaul. However, operators should be aware that some of the existing trunnion pin assemblies require modification. Figures 9, 11, and 12 of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, provide instructions for modifying certain pin assemblies. Note (c) in each of these figures refers to paragraph 2.C.3., "Parts Modified and Reidentified," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, which shows the existing and modified part numbers. For use of other part numbers, such as those identified in the Boeing 737 Aircraft Illustrated Parts Catalog or Boeing Drawing 161A0002, "Boeing Model 737–NG Main Landing Gear Component Interchangeability List," operators may request an alternative method of compliance in accordance with the procedures specified in paragraph (m) of this AD. We have not changed this AD regarding this issue.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. The service information describes procedures for lubricating the forward and aft trunnion pin assemblies on the left and right MLGs, inspecting the forward and aft trunnion pin assemblies for corrosion or damage, and performing corrective actions. In addition, the service information describes procedures for installing a new forward trunnion pin housing assembly, seal, and retainer configuration. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 1,023 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Lubrication	2 work-hours × $85 per hour = $170, per lubrication cycle.	$0	$170	$173,910, per lubrication cycle (1,023 airplanes).
Inspection (Groups 1 and 2, Configuration 1 airplanes).	51 work-hours × $85 per hour = $4,335, per inspection cycle.	0	4,335	4,282,980, per inspection cycle (988 airplanes).
Inspection (Group 3 airplanes)	93 work-hours × $85 per hour = $7,905, per inspection cycle.	0	7,905	276,675, per inspection cycle (35 airplanes).
Replacement/overhaul (Groups 1 and 2 airplanes).	84 work-hours × $85 per hour = $7,140.	0	7,140	7,054,320 (988 airplanes).
Replacement/overhaul (Group 3 airplanes).	86 work-hours × $85 per hour = $7,310.	0	7,310	255,850 (35 airplanes).

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–18–01 The Boeing Company: Amendment 39–18631; Docket No. FAA–2015–8133; Directorate Identifier 2015–NM–101–AD.

(a) Effective Date

This AD is effective October 5, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to certain The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/184DE9A71EC3FA55862 57EAE00707DA6?OpenDocument&Highlight =st00830se*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by reports of heavy corrosion and chrome damage of the forward and aft trunnion pin assemblies of the right and left main landing gears (MLGs). We are issuing this AD to detect and correct heavy corrosion and chrome damage of the forward and aft trunnion pin assemblies of the right and left MLGs, which could result in cracking of these assemblies and collapse of the MLGs.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Lubrication of MLG Trunnion Pin Assemblies

For airplanes in Groups 1 and 2, Configuration 1, and airplanes in Group 3, as identified in Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015: Except as required by paragraph (k) of this AD, at the applicable time specified in Table 1 or Table 2 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, lubricate the forward and aft trunnion pin assemblies of the left and right MLGs, in accordance with Work Package 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. Repeat the lubrication thereafter at intervals not to exceed those specified in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. Accomplishment of the actions specified in paragraph (i) of this AD terminates the repetitive lubrication required by this paragraph.

(h) Repetitive Inspections, Corrective Actions, and Lubrication

For airplanes in Groups 1 and 2, Configuration 1, and airplanes in Group 3, as identified in Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015: Except as required by paragraph (k) of this AD, at the applicable time specified in Table 1 or Table 2 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, do a general visual inspection of the left and right MLGs at the forward and aft trunnion pin locations and the visible surfaces of the forward and aft trunnion pin assemblies for signs of corrosion or chrome plating damage and lubricate the forward and aft trunnion pin assemblies, in accordance with Work Package 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. Repeat the general visual inspection thereafter at intervals not to exceed those specified in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015. If any discrepancy is found during any inspection required by this paragraph, before further flight, do all applicable related investigative and corrective actions in accordance with Work Package 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737 32–1448, Revision 1, dated May 29, 2015. Accomplishment of the actions required by paragraph (i) of this AD terminates the repetitive inspections required by this paragraph.

(i) Modification of MLG Trunnion Pin Assemblies

For airplanes in Groups 1 and 2, Configuration 1, and airplanes in Group 3, as identified in Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015: Except as required by paragraph (k) of this AD, at the applicable time specified in Table 1 or Table 2 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, modify and lubricate the left and right MLG trunnion pin assemblies, and do all applicable related investigative and corrective actions, in accordance with Work Package 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015.

Accomplishment of the actions in Work Package 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, terminates the repetitive lubrication required by paragraph (g) of this AD and the repetitive inspections required by paragraph (h) of this AD.

(j) Replacement of MLG Forward Trunnion Pin Housing Assembly, Seal, and Retainer

For airplanes in Groups 1 and 2, Configuration 2, as identified in Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015: At the applicable time specified in Table 3 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, replace the seal, retainer, and support ring assembly with a new seal and retainer configuration; install the forward trunnion pin assembly into the housing assembly; and lubricate the forward and aft trunnion pin assemblies for the left and right MLGs; in accordance with Work Package 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015.

(k) Exception to Service Information Specification

Where paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015, specifies a compliance time "from the original issue date on this service bulletin," this AD requires compliance within the specified compliance time "after the effective date of this AD."

(l) Credit for Previous Actions

This paragraph provides credit for the requirements of paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 737–32–1448, dated May 19, 2011, which is not incorporated by reference in this AD.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (n)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(n) Related Information

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM–120S, FAA Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6450; fax: 425–917–6590; email: *alan.pohl@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 737–32–1448, Revision 1, dated May 29, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20686 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9047; Directorate Identifier 2016–NM–092–AD; Amendment 39–18632; AD 2016–18–02]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 777–200 and –300ER series airplanes. This AD requires replacing the low-pressure oxygen flex hoses with new non-conductive low-pressure oxygen flex hoses in the gaseous passenger oxygen system in airplanes equipped with therapeutic oxygen. This AD was prompted by a determination that the low-pressure oxygen flex hoses in the gaseous passenger oxygen system can potentially be conductive. We are issuing this AD to prevent electrical current from passing through the low-pressure oxygen flex hoses in the gaseous passenger oxygen system, which can cause the flex hoses to melt or burn, and a consequent oxygen-fed fire in the passenger cabin.

DATES: This AD is effective September 15, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 15, 2016].

We must receive comments on this AD by October 17, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9047.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9047; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA; phone: 425–917–6457; fax: 425–917–6590; email: *susan.l.monroe@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

This AD was prompted by a determination that the low-pressure oxygen flex hoses in the gaseous passenger oxygen system can potentially be conductive. Conductive oxygen hoses in the flight compartment were addressed previously in AD 2012–13–05, Amendment 39–17107 (77 FR 41045, July 12, 2012).

The gaseous passenger oxygen system equipped with therapeutic oxygen is not continuously pressurized and must be activated by the flightcrew. Exposure to electrical faults, such as unintended short circuits, can result in localized electrical heating of the low-pressure oxygen flex hoses. This condition, if not corrected, could result in electrical current passing through the low-pressure oxygen flex hoses, which can cause flex hoses to melt or burn, and a consequent oxygen-fed fire in the passenger cabin.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016. The service information describes procedures for replacing the low-pressure oxygen flex hoses with new non-conductive low-pressure oxygen flex hoses in the gaseous passenger oxygen system in airplanes equipped with therapeutic oxygen. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016. For information on the procedures, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9047.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of this product. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2016–9047 and Directorate Identifier 2016–NM–092–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, we provide the following cost estimates to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	33 work-hours × $85 per hour = $2,805	$15,173	$17,978

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs" describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–18–02 The Boeing Company: Amendment 39–18632; Docket No. FAA–2016–9047; Directorate Identifier 2016–NM–092–AD.

(a) Effective Date

This AD is effective September 15, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 777–200 and –300ER series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Unsafe Condition

This AD was prompted by a determination that the low-pressure oxygen flex hoses in the gaseous passenger oxygen system in airplanes equipped with therapeutic oxygen can potentially be conductive. We are issuing this AD to prevent electrical current from passing through the low-pressure oxygen flex hoses in the gaseous passenger oxygen system, which can cause the flex hoses to melt or burn, and a consequent oxygen-fed fire in the passenger cabin.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement

Within 72 months after the effective date of this AD: Replace the low-pressure oxygen flex hoses with new non-conductive low-pressure oxygen flex hoses in the gaseous passenger oxygen system in airplanes equipped with therapeutic oxygen, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install on any airplane a low-pressure oxygen flex hose having a part number that is specified to be removed from an airplane in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled "RC Exempt," then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

For more information about this AD, contact Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA; phone: 425–917–6457; fax: 425–917–6590; email: *susan.l.monroe@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 777–35–0041, dated April 8, 2016.

(ii) Reserved.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20722 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5467; Directorate Identifier 2015–NM–186–AD; Amendment 39–18630; AD 2016–17–17]

RIN 2120–AA64

Airworthiness Directives; Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Defense and Space S.A. Model CN–235, CN–235–200, and CN–235–300 airplanes. This AD was prompted by reports of main landing gear (MLG) access doors detaching from the airplane as a result of excessive vibration and metal fatigue in the attach fittings. This AD requires modification of the MLG access door by replacing seals in the MLG fairing and, for certain airplanes, adding an additional bolt. We are issuing this AD to prevent a fracture in the MLG access door associated with excessive vibration and metal fatigue in the attach fittings. This condition could lead to MLG access door detachment and consequent impact of flight controls, resulting in reduced control of an airplane.

DATES: This AD is effective October 5, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 5, 2016.

ADDRESSES: For service information identified in this final rule, contact EADS–CASA, Military Transport Aircraft Division (MTAD), Integrated Customer Services (ICS), Technical Services, Avenida de Aragón 404, 28022 Madrid, Spain; telephone +34 91 585 55 84; fax +34 91 585 55 05; email *MTA.TechnicalService@casa.eads.net;* Internet *http://www.eads.net.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5467.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5467; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM 116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1112; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Defense and Space S.A. Model CN–235, CN–235–200, and CN–235–300 airplanes. The NPRM published in the **Federal Register** on April 13, 2016 (81 FR 21766) (“the NPRM”). The NPRM was prompted by reports of MLG access doors detaching from the airplane as a result of excessive vibration and metal fatigue in the attach fittings. The NPRM proposed to require modification of the MLG access door by replacing seals in the MLG fairing and, for certain airplanes, adding an additional bolt. We are issuing this AD to prevent a fracture in the MLG access door associated with excessive vibration and metal fatigue in the attach fittings. This condition could lead to MLG access door detachment and consequent impact of flight controls, resulting in reduced control of an airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued Airworthiness Directive 2015–0225, dated November 18, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Airbus Defense and Space S.A. Model CN–235, CN–235–200, and CN–235–300 airplanes. The MCAI states:

> Occurrences of Main Landing Gear (MLG) Access Door detachment were reported. Subsequent investigation determined that the detachments of the MLG Door occurred during maneuvers performed at high speed and with high sideslip angle on airplanes not modified in accordance with the instructions EADS–CASA Service Bulletins (SBs) SB–235–52–0061 and SB–235–52–0068. Based on the investigation results, it was determined that the fracture mechanism was associated with excessive deformation that could produce scooping in the forward edge combined with an excessive vibration of the MLG Access Door.
>
> This condition, if not corrected, could lead to MLG Access Door detachment and consequent impact of flight controls, resulting in reduced control of an airplane and possible injury of persons on the ground.
>
> To address this potential unsafe condition, EADS–CASA issued SB–235–52–0061 and SB–235–52–0068 to provide modification instructions.
>
> For the reasons described above, this [EASA] AD requires modification of MLG Access Doors and prohibits installation of a MLG Access Door sealing part number (P/N) CAN36032R. This [EASA] AD also prohibits installation of not modified MLG Access Doors.

Required actions include modification of the MLG access door by replacing seals in the MLG fairing and, for certain airplanes, adding an additional bolt. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5467.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We have reviewed the following service information:

- EADS CASA Service Bulletin SB–235–52–0061, Revision 1, dated October 24, 2014. The service information describes procedures for modifying the MLG access door by installing an additional bolt.
- EADS CASA Service Bulletin SB–235–52–0068, Revision 2, dated January

9, 2015. The service information describes procedures for modifying the MLG access door by installing an improved fairing seal.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 30 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification	60 work-hours × $85 per hour = $5,100	$12,684	$17,784	$533,520

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–17–17 Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.): Amendment 39–18630; Docket No. FAA–2016–5467; Directorate Identifier 2015–NM–186–AD.

(a) Effective Date

This AD is effective October 5, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Defense and Space S.A. (formerly known as Construcciones Aeronauticas, S.A.) Model CN–235, CN 235–200, and CN 235–300 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by reports of main landing gear (MLG) access doors detaching from the airplane as a result of excessive vibration and metal fatigue in the attach fittings. We are issuing this AD to prevent a fracture in the MLG access door associated with excessive vibration and metal fatigue in the attach fittings. This condition could lead to MLG access door detachment and consequent impact of flight controls, resulting in reduced control of an airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Modifications

(1) For all airplanes: Within 12 months after the effective date of this AD, modify each MLG access door by installing an improved fairing seal, in accordance with the Accomplishment Instructions of EADS CASA Service Bulletin SB–235–52–0068, Revision 2, dated January 9, 2015.

(2) For all Model CN–235–200 airplanes: Concurrently with the action required in paragraph (g)(1) of this AD, modify each affected MLG access door by installing an additional bolt, in accordance with the Accomplishment Instructions of EADS CASA Service Bulletin SB–235–52–0061, Revision 1, dated October 24, 2014.

(h) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraph (g)(1) of this AD, if those actions were performed before the effective date of this AD, using EADS CASA Service Bulletin SB–235–52–0068, Revision 1, dated October 24, 2014; or SB–235–52–0068, dated July 15, 2002.

(2) This paragraph provides credit for actions required by paragraph (g)(2) of this AD, if those actions were performed before the effective date of this AD using EADS CASA Service Bulletin SB–235–52–0061, dated October 31, 1996.

(i) Parts Installation Prohibition and Limitation

(1) For airplanes modified as specified in paragraphs (g)(1) and (g)(2) of this AD, as applicable, before the effective date of this AD: As of the effective date of this AD, no person may install a seal having part number CAN36032R on any MLG access door.

(2) For airplanes not modified as specified in paragraphs (g)(1) and (g)(2) of this AD, as applicable, before the effective date of this AD: After accomplishing the actions required by paragraphs (g)(1) and (g)(2) of this AD, as applicable, no person may install a seal having part number CAN36032R on any MLG access door.

(3) As of the effective date of this AD, installation of an MLG access door on an airplane is allowed, provided the MLG access door is modified as required by paragraphs (g)(1) and (g)(2) of this AD, as applicable.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to

approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1112; fax 425–227–1149. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus Defense and Space S.A.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2015–0225, dated November 18, 2015, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5467.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (l)(4) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) EADS CASA Service Bulletin SB–235–52–0061, Revision 1, Dated October 24, 2014.

(ii) EADS CASA Service Bulletin SB–235–52–0068, Revision 2, dated January 9, 2015.

(3) For service information identified in this AD, contact EADS–CASA, Military Transport Aircraft Division (MTAD), Integrated Customer Services (ICS), Technical Services, Avenida de Aragón 404, 28022 Madrid, Spain; telephone +34 91 585 55 84; fax +34 91 585 55 05; email *MTA.TechnicalService@casa.eads.net;* Internet *http://www.eads.net.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20706 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1075; Directorate Identifier 2012–NM–111–AD; Amendment 39–18628; AD 2016–17–15]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. This AD was prompted by the need for more stringent inspection requirements for certain affected components. This AD requires revising the maintenance or inspection program to incorporate certain revised airworthiness limitations (AWL) and require repairs of affected components. We are issuing this AD to detect and correct fatigue cracking in the affected components; such cracking could result in loss of structural integrity.

DATES: This AD is effective October 5, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 5, 2016.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* Internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–1075.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–1075; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jeffrey Zimmer, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7306; fax: 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The SNPRM published in the **Federal Register** on October 27, 2015 (80 FR 65666) ("the SNPRM"). We preceded the SNPRM with a notice of proposed rulemaking (NPRM) that published in the **Federal Register** on October 16, 2012 (77 FR 63282) ("the NPRM"). The NPRM proposed to require revising the maintenance or inspection program to incorporate revised AWL tasks specified in certain technical requirements. The NPRM was prompted by the need for more stringent inspection requirements for certain affected components. The SNPRM proposed to require revising the maintenance or inspection program to incorporate certain revised AWL tasks instead of TRs, and to require repairs of affected components. We are issuing this AD to detect and correct fatigue cracking in the affected components. Such cracking could result in loss of structural integrity.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2012–13, dated April 10, 2012 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states:

> A revision has been made to Part 2 of the Canadair Regional Jet Maintenance Requirements Manual (MRM), Airworthiness Limitations (AWL), to introduce more stringent inspection requirements for continued airworthiness based on re-analysis, in-service data and/or fatigue testing. Failure to comply with these revised AWL items could lead to an unsafe condition.
>
> This [Canadian] AD is issued to ensure that fatigue cracking of these affected components [and consequent loss of airplane structural integrity] is detected and corrected.

Required actions include revising the maintenance program by incorporating the revised inspection requirements specified in certain TRs. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–1075.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Request To Withdraw SNPRM

Mr. Aaron Ahern stated that the SNPRM must be denied and considered null and void. Mr. Ahern provided no justification for this statement.

From this statement, we infer that Mr. Ahern is requesting we withdraw the SNPRM. We disagree with the request. It is within our authority to issue ADs to require actions to address unsafe conditions that are not otherwise being addressed (or are not addressed adequately) by normal maintenance procedures. We may address such unsafe conditions by requiring revisions to maintenance or inspection programs as a condition under which airplanes may continue to be operated. We agree with TCCA's finding of an unsafe condition based on analysis, in-service data, and/or fatigue testing. From the data gathered, we have determined that fatigue cracking is likely to exist or develop in certain components of the affected airplanes. As a result, we have determined that the actions required by this AD are necessary to address the identified unsafe condition. We have not changed this final rule in this regard.

Request To Allow for Other Methods of Compliance

Air Wisconsin Airlines Corporation (Air Wisconsin) requested that we revise the proposed AD to allow qualified FAA representatives, such as Designated Engineering Representatives (DERs) and Organization Designation Authorization (ODA) holders, to approve repair methods. Air Wisconsin stated that 14 CFR 121.1109 (Supplemental Inspections) requires a certificate holder's maintenance program to include FAA-approved damage tolerance inspections and procedures. Air Wisconsin pointed out that both DERs and ODAs already perform damage tolerance evaluations (DTEs).

We disagree. While we might authorize a design approval holder's DERs to determine whether a design or repair method complies with a specific requirement of a structural AD, they are not authorized to make the discretionary determination of the applicable requirement. DERs are not authorized to approve repairs as alternative methods of compliance (AMOCs) to ADs, except under specific conditions described in FAA Orders 8110.103, 8100.15, and 8100.37. In addition, this AD already includes a provision for TCCA's Design Approval Organization (DAO) to approve repairs. We have not changed this AD in this regard.

Request To Confirm Previously Approved Repairs

Air Wisconsin requested that we confirm whether repairs that may not have been incorporated per paragraphs (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of the proposed AD (in the SNPRM) are still considered approved for compliance to this AD under paragraph (k)(2) of the proposed AD (in the SNPRM).

We agree. As long as the previously approved repair meets the requirements of paragraphs (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of this AD, it does not matter when the repair is actually accomplished. We have clarified paragraph (k)(2)(i) of this AD to reflect this. In response to Air Wisconsin's comment regarding this issue in the NPRM, we had included a provision in paragraph (k)(2)(i) of the proposed AD (in the SNPRM) to allow for previously approved repairs in the inspection area that were approved by the Manager, New York Aircraft Certification Office, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO, but that provision included the language "the repairs were accomplished." We have removed that language from paragraph (k)(2)(i) of this AD.

Request To Reference Revised Service Information

SkyWest Airlines (SkyWest) requested that we revise the SNPRM to reference the latest service information. SkyWest pointed out that Bombardier has issued Revision 10, dated May 10, 2015, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual (MRM), CSP A–053.

We agree to reference Bombardier Revision 10, dated May 10, 2015, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 MRM, CSP A–053, as the appropriate source of service information for certain requirements of this AD. We have revised this final rule accordingly.

Request To Remove Requirement That Repair Approvals Refer to the MCAI

SkyWest requested that we remove the requirement that repair approvals must refer to the MCAI. SkyWest stated that leaving this paragraph in the AD would require SkyWest to request a large number of AMOCs for their fleet as soon as the AD becomes effective. SkyWest asserts that none of the repair engineering orders (REOs) and general repair engineering orders (GREOs) reference the MCAI, and do not have an inspection method.

We disagree with the request. We are aware of instances of repairs in an affected area that are signed by the foreign authority's authorized delegate, but did not correct the unsafe condition because they were outdated. A repair that references the unsafe condition addressed in the MCAI guarantees an approved repair. A revised service document or AMOC that satisfies the requirements of paragraph (k)(2) of this AD is acceptable. We have not changed this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Appendix B—Airworthiness Limitations, of Part 2 Airworthiness Requirements, Revision 10, dated May 10, 2015, of the Bombardier CL–600–2B19 Maintenance Requirements Manual (MRM) CSP A–053. Appendix B provides specific AWLs, including the following AWLs.

- AWL 52–11–131, "Passenger door—piano hinge half on door side." This AWL describes procedures for a detailed visual inspection of the piano hinge half on the passenger door side.
- AWL 53–11–122, "Windshield center post and bulkhead aft post at FS202.75." This AWL describes procedures for a special detailed inspection of the windshield center post and bulkhead aft post at fuselage station (FS) 202.75.
- AWL 53–21–118, "Potable water servicing door cut–out and internal structure." This AWL describes procedures for a detailed visual inspection of the potable water servicing door cut-out and internal structure.
- AWL 53–21–129, "Passenger door—piano hinge half on fuselage side." This AWL describes procedures for a detailed visual inspection of the piano hinge half of the passenger door on the fuselage side.
- AWL 53–41–199, "FS409.0 +128 vertical posts at BL0.0 and BL18.0 left and right local to WL69.0." This AWL describes procedures for a special detailed inspection of the FS409.0 +128 left and right vertical posts at buttock line (BL) 0.0 and BL18.0 local to water line (WL) 69.0.
- AWL 53–41–200, "FS409.0 +128 frame cap aft and fwd splice angles at STR21 left and right." This AWL describes procedures for a detailed visual inspection of the FS409.0 +128 frame cap aft and forward splice angles at stringer 21.
- AWL 53–41–201, "FS559.0 pressure bulkhead web and cap angle local to BL9.0 and BL18.0 left and right." This AWL describes procedures for a special detailed inspection of the left and right FS559.0 pressure bulkhead web and cap angle local to BL9.0 and BL18.0.
- AWL 53–61–156, "Rear pressure bulkhead forward face below floor." This AWL describes procedures for a special detailed inspection of the below floor forward face of the rear pressure bulkhead.
- AWL 54–10–105, "Pylon track and support fitting." This AWL describes procedures for a special detailed inspection of the pylon track and support fitting.
- AWL 54–10–106, "Pylon track and support fitting." This AWL describes procedures for a special detailed inspection of the pylon track and support fitting.
- AWL 57–21–105, "Lower wing skin, between BL0.0 to wing station (WS) 314.0." This AWL describes procedures for a detailed visual inspection of the lower wing skin, between BL0.0 to WS314.0.
- AWL 57–21–112, "Lower wing plank splice joints at BL45.0, WS65.75, and WS148.0." This AWL describes procedures for a special detailed inspection of the lower wing plank splice joints at BL45.0, WS65.75, and WS148.0.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 575 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Cost per product	Cost on U.S. operators
Revising maintenance program	1 work-hour × $85 per hour = $85	$85	$48,875

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–17–15 Bombardier, Inc: Amendment 39–18628. Docket No. FAA–2012–1075; Directorate Identifier 2012–NM–111–AD.

(a) Effective Date

This AD is effective October 5, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, serial numbers 7003 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 05, Periodic inspections.

(e) Reason

This AD was prompted by the need for more stringent inspection requirements for certain affected components. We are issuing this AD to detect and correct fatigue cracking in the affected components, which could result in loss of structural integrity.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance Program or Inspection Program Revision

Within 60 days after the effective date of this AD: Revise the maintenance or inspection program, as applicable, to incorporate the revised inspection requirements specified in the AWLs identified in paragraphs (g)(1) through (g)(12) of this AD. These AWLs are identified in Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, Revision 10, dated May 10, 2015, of the Bombardier CL–600–2B19 Maintenance Requirements Manual (MRM) CSP A–053.

(1) AWL 52–11–131, "Passenger door—piano hinge half on door side."

(2) AWL 53–11–122, "Windshield center post and bulkhead aft post at FS202.75."

(3) AWL 53–21–118, "Potable water servicing door cut–out and internal structure."

(4) AWL 53–21–129, "Passenger door—piano hinge half on fuselage side."

(5) AWL 53–41–199, "FS409.0+128 vertical posts at BL0.0 and BL18.0 left and right local to WL69.0."

(6) AWL 53–41–200, "FS409.0+128 frame cap aft and fwd splice angles at STR21 left and right."

(7) AWL 53–41–201, "FS559.0 pressure bulkhead web and cap angle local to BL9.0 and BL18.0 left and right."

(8) AWL 53–61–156, "Rear pressure bulkhead forward face below floor."

(9) AWL 54–10–105, "Pylon track and support fitting."

(10) AWL 54–10–106, "Pylon track and support fitting."

(11) AWL 57–21–105, "Lower wing skin, between BL0.0 to WS314.0."

(12) AWL 57–21–112, "Lower wing plank splice joints at BL45.0, WS65.75, and WS148.0."

(h) Initial Compliance Times for AWL Tasks

(1) For tasks with phase-in schedules specified in the AWLs identified in paragraphs (g)(1) through (g)(12) of this AD: The initial compliance times are at the applicable times specified in the applicable AWL, or within 60 days after the effective date of this AD, whichever occurs later, except as specified in paragraph (h)(2) of this AD.

(2) For tasks with no phase-in schedules specified in the AWLs identified in paragraphs (g)(1) through (g)(12) of this AD: The initial compliance times are at the applicable times specified in Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, Revision 10, dated May 10, 2015, of the Bombardier CL–600–2B19 MRM CSP A–053; or within 1,000 flight cycles after the effective date of this AD; whichever occurs later.

(i) Corrective Action

If any damage (including, but not limited to, cracking, corrosion, and wear) is found during any inspection required by any AWL specified in paragraph (g) of this AD: Before further flight, repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(j) No Alternative Actions or Intervals

After accomplishing the revisions required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used other than those specified in the AWLs identified in paragraphs (g)(1) through (g)(12) of this AD; unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in paragraph (k) of this AD, or the actions and intervals are approved as part of a repair specified in paragraph (i) of this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Previously Approved Repairs:* Repairs approved before the effective date of this AD that meet the conditions specified in paragraphs (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of this AD are acceptable methods of compliance for the repaired area.

(i) The repairs were approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO.

(ii) The repair approval refers to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2012–13, dated April 10, 2012, and provides an inspection program (inspection threshold, method, and repetitive interval).

(iii) The operator has revised its maintenance or inspection program, as applicable, to include the inspection program (inspection threshold, method, and repetitive interval) for the repair.

(3) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(l) Related Information

Refer to MCAI Canadian AD CF–2012–13, dated April 10, 2012, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–1075.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual, Revision 10, dated May 10, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* Internet: *http://www.bombardier.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20707 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6415; Directorate Identifier 2015–NM–178–AD; Amendment 39–18626; AD 2016–17–13]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes. This AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. This AD requires a revision of the airplane flight manual (AFM) emergency procedures section to provide procedures to guide the crew on how to stabilize the airplane airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. We are issuing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

DATES: This AD is effective October 5, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 5, 2016.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Assata Dessaline, Aerospace Engineer, Avionics and Services Branch, ANE–172, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7301; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes. The NPRM published in the **Federal Register** on May 10, 2016 (81 FR 28768) (“the NPRM”). The NPRM was prompted by two in-service incidents of a loss of all air data information in the flight deck. The NPRM proposed to require a revision of the AFM emergency procedures section to provide procedures to guide the crew on how to stabilize the airplane airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. We are issuing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2015–20, dated July 21, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes. The MCAI states:

> Two in-service incidents have been reported on CL–600–2C10 aeroplanes regarding a loss of all air data information in the cockpit. The air data information was recovered as the aeroplane descended to lower altitudes. An investigation determined that the root cause in both events was high altitude icing (ice crystal contamination). If not addressed, this condition may affect continued safe flight.
>
> Due to similarities in the air data systems, such events could happen on all Bombardier CRJ models, CL–600–2B19, CL–600–2C10, CL–600–2D15, CL–600–2D24 and CL–600–2E25. Therefore, the corrective actions for these models will be mandated once their respective Airplane Flight Manual (AFM) revisions become available.
>
> This [Canadian] AD mandates the incorporation of AFM procedures to guide the crew to stabilize the aeroplane's airspeed and attitude for continued safe flight.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Section 03–19, “Unreliable Airspeed,” of Chapter 3, “Emergency Procedures,” in the Bombardier CRJ Series Regional Jet Model CL–600–2C10 Airplane Flight Manual CSP B–012, Revision 16A, dated November 6, 2015. The service information describes procedures to guide the crew to stabilize the airplane's airspeed and attitude for continued safe flight when a loss of all air data information has occurred in the flight deck. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 269 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revision	1 work-hour × $85 per hour = $85	$0	$85	$22,865

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–17–13 Bombardier, Inc.: Amendment 39–18626; Docket No. FAA–2016–6415; Directorate Identifier 2015–NM–178–AD.

(a) Effective Date

This AD is effective October 5, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, certificated in any category, serial numbers 10002 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by two in-service incidents of a loss of all air data information in the flight deck. We are issuing this AD to prevent loss of control when a loss of all air data information has occurred in the flight deck.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Airplane Flight Manual (AFM) Revision

Within 30 days after the effective date of this AD, revise the emergency procedures section of the AFM by incorporating Section 03–19, "Unreliable Airspeed," of Chapter 3, "Emergency Procedures," in the Bombardier CRJ Series Regional Jet Model CL–600–2C10 Airplane Flight Manual CSP B–012, Revision 16A, dated November 6, 2015.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–20, dated July 21, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6415.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Section 03–19, "Unreliable Airspeed," of Chapter 3, "Emergency Procedures," in the Bombardier CRJ Series Regional Jet Model CL–600–2C10 Airplane Flight Manual CSP B–012, Revision 16A, dated November 6, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20680 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 310

RIN 3084–AA98

Telemarketing Sales Rule Fees

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (the "Commission" or "FTC") is amending its Telemarketing Sales Rule ("TSR") by updating the fees charged to entities accessing the National Do Not Call Registry (the "Registry") as required by the Do-Not-Call Registry Fee Extension Act of 2007.

DATES: The revised fees will become effective October 1, 2016.

ADDRESSES: Copies of this document are available on the Internet at the Commission's Web site: *http://www.ftc.gov.*

FOR FURTHER INFORMATION CONTACT: Ami Joy Dziekan, (202) 326–2648, BCP, Federal Trade Commission, 600 Pennsylvania Avenue NW., Room CC–9225, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: To comply with the Do-Not-Call Registry Fee Extension Act of 2007 (Pub. L. 110–188, 122 Stat. 635) ("Act"), the Commission is amending the TSR by updating the fees entities are charged for accessing the Registry as follows: The revised rule increases the annual fee for access to the Registry for each area code of data from $60 to $61 per area code; increases the maximum amount that will be charged to any single entity for accessing area codes of data from $16,482 to $16,714; and the fee per area code of data during the second six months of an entity's annual subscription period remains $30.

These increases are in accordance with the Act, which specifies that beginning after fiscal year 2009, the dollar amounts charged shall be increased by an amount equal to the amounts specified in the Act, multiplied by the percentage (if any) by which the average of the monthly consumer price index (for all urban consumers published by the Department of Labor) ("CPI") for the most recently ended 12-month period ending on June 30 exceeds the CPI for the 12-month period ending June 30, 2008. The Act also states that any increase shall be rounded to the nearest dollar and that there shall be no increase in the dollar amounts if the change in the CPI is less than one percent. For fiscal year 2009, the Act specified that the original annual fee for access to the Registry for each area code of data was $54 per area code, or $27 per area code of data during the second six months of an entity's annual subscription period, and that the maximum amount that would be charged to any single entity for accessing area codes of data would be $14,850.

The determination whether a fee change is required and the amount of the fee change involves a two-step process. First, to determine whether a fee change is required, we measure the change in the CPI from the time of the previous increase in fees. The last fees increase was for fiscal year 2015. Accordingly, we calculated the change in the CPI since fiscal year 2015, and the increase was 1.41 percent. Because this change is over the one percent threshold, the fees will change for fiscal year 2017.

Second, to determine how much the fees should increase this fiscal year, we use the calculation specified by the Act set forth above, the percentage change in the baseline CPI applied to the original fees for fiscal year 2009. The average value of the CPI for July 1, 2007 to June 30, 2008 was 211.702; the average value for July 1, 2015 to June 30, 2016 was 238.276, an increase of 12.55 percent. Applying the 12.55 percent increase to the base amount from fiscal year 2009, leads to an increase from $60 to $61 in the fee from last year for access to a single area code of data for a full year for fiscal year 2017. The actual amount is $60.78, but when rounded, pursuant to the Act, the amount is $61. The fee for accessing an additional area code for a half year remains $30 (rounded from $30.39). The maximum amount charged increases to $16,714 (rounded from $16,713.68).

Administrative Procedure Act; Regulatory Flexibility Act; Paperwork Reduction Act. The revisions to the Fee Rule are technical in nature and merely incorporate statutory changes to the TSR. These statutory changes have been adopted without change or interpretation, making public comment unnecessary. Therefore, the Commission has determined that the notice and comment requirements of the Administrative Procedure Act do not apply. *See* 5 U.S.C. 553(b). For this reason, the requirements of the Regulatory Flexibility Act also do not apply. *See* 5 U.S.C. 603, 604.

Pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501–3521, the Office of Management and Budget ("OMB") approved the information collection requirements in the Amended TSR and assigned the following existing OMB Control Number: 3084–0097. The amendments outlined in this Final Rule pertain only to the fee provision (§ 310.8) of the Amended TSR and will not establish or alter any record keeping, reporting, or third-party disclosure requirements elsewhere in the Amended TSR.

List of Subjects in 16 CFR Part 310

Advertising, Consumer protection, Reporting and recordkeeping requirements, Telephone, Trade practices.

Accordingly, the Federal Trade Commission amends part 310 of title 16 of the Code of Federal Regulations as follows:

PART 310—TELEMARKETING SALES RULE

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 15 U.S.C. 6101–6108; 15 U.S.C. 6151–6155.

■ 2. In § 310.8, revise paragraphs (c) and (d) to read as follows:

§ 310.8 Fee for access to the National Do Not Call Registry.

* * * * *

(c) The annual fee, which must be paid by any person prior to obtaining access to the National Do Not Call Registry, is $61 for each area code of data accessed, up to a maximum of $16,714; *provided,* however, that there shall be no charge to any person for accessing the first five area codes of data, and *provided further,* that there shall be no charge to any person engaging in or causing others to engage in outbound telephone calls to consumers and who is accessing area codes of data in the National Do Not Call Registry if the person is permitted to access, but is not required to access, the National Do Not Call Registry under this Rule, 47 CFR 64.1200, or any other Federal regulation or law. No person may participate in any arrangement to share the cost of accessing the National Do Not Call Registry, including any arrangement with any telemarketer or service provider to divide the costs to access the registry among various clients of that telemarketer or service provider.

(d) Each person who pays, either directly or through another person, the annual fee set forth in paragraph (c) of this section, each person excepted under paragraph (c) from paying the annual fee, and each person excepted from paying an annual fee under § 310.4(b)(1)(iii)(B), will be provided a unique account number that will allow that person to access the registry data for the selected area codes at any time for the twelve month period beginning on the first day of the month in which the person paid the fee ("the annual period"). To obtain access to additional area codes of data during the first six months of the annual period, each person required to pay the fee under paragraph (c) must first pay $61 for each additional area code of data not initially selected. To obtain access to additional area codes of data during the second six months of the annual period, each person required to pay the fee under paragraph (c) must first pay $30 for each additional area code of data not initially selected. The payment of the additional fee will permit the person to access the additional area codes of data for the remainder of the annual period.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–20817 Filed 8–30–16; 8:45 am]

BILLING CODE 6750–01–P

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1304

When Obstructions on Certain Tributaries of the Tennessee River Do Not Require a Section 26a Permit from the Tennessee Valley Authority

AGENCY: Tennessee Valley Authority.

ACTION: Interpretive Rule.

SUMMARY: The Tennessee Valley Authority (TVA) is issuing guidance stating that certain structures, while obstructions across, along, or in certain tributaries of the Tennessee River, do not need a Section 26a permit from TVA, because they have an indiscernible effect on navigation, flood control or public lands or reservations.

DATES: Effective August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Rebecca C. Tolene, Vice President, Natural Resources, Tennessee Valley Authority, Knoxville, Tennessee (865–632–4433).

SUPPLEMENTARY INFORMATION:

I. Legal Authority

This interpretive rule is promulgated under the authority of the TVA Act, as amended, 16 U.S.C. 831–831ee.

II. Background

Section 26a of the TVA Act requires that TVA's approval be obtained prior to the construction, operation, or maintenance of any dam, appurtenant works, or other obstruction affecting navigation, flood control, or public lands or reservations across, along, or in the Tennessee River or any of its tributaries. 16 U.S.C. 831y–1 (2012). TVA's rules governing such approval are codified at 18 CFR part 1304. The rules include a permitting process whereby applicants may request from TVA a permit for various structures such as boat docks, piers, shoreline stabilization projects, dams, and bridges, all of which qualify as "obstructions" under TVA's regulations. An obstruction is generally any man-made physical condition that during its continuance after completion impounds, checks, hinders, restricts, retards, diverts, or otherwise interferes with the movement of water or of objects on or in the water. Over the years, TVA has found that certain obstructions because of their location, the nature of their construction, or both have not discernibly interfered with the operation or management of the TVA reservoir system. In particular, this has occurred at locations across, along, or in certain tributary reaches that are upstream of the control or influence of TVA's reservoir system operations. For the purpose of this rule, these are called upstream tributary reaches. At these locations, certain obstructions have an indiscernible impact on water surface elevations in the reservoir system or the flow or volume of water entering the reservoir system and thereby do not materially interfere with TVA's flood control or navigation responsibilities. Furthermore, at these locations, TVA does not typically own property and therefore construction does not affect or interfere with the management of TVA's property. These obstructions include, but are not limited to, stream bank stabilization, bridges and culverts, stream crossings, fences, launching ramps, boat docks, piers, and certain fills and intakes. For these reasons, TVA has determined that certain obstructions do not require approval pursuant to Section 26a of the TVA Act when located across, along, or in an upstream tributary reach of the Tennessee River.

Conversely, based on years of permitting experience, TVA has found that other obstructions across, along, or in upstream tributary reaches do potentially interfere with the management of TVA's reservoir system. These include, but are not limited to, structures such as dams, impoundments, interbasin transfers and certain water intakes. TVA will continue to require approval of these and other obstructions not set forth in Section III of this Interpretive Rule, when located across, along, or in an upstream tributary reach.

The Tennessee River has a 41,000-square-mile drainage basin. Thousands of miles of upstream tributary reaches ultimately flow into the Tennessee River, making it impractical to identify each upstream tributary reach in this rule. For the purpose of this rule, upstream tributary reaches do *not* include the following:

(1) The Tennessee River;

(2) TVA reservoirs, (TVA reservoirs are listed in Table 1);

(3) stream reaches within a TVA reservoir, the 500-year floodplain of the Tennessee River, or both;

(4) stream reaches downstream of a TVA dam (these reaches are listed in Table 2); and

(5) stream reaches where TVA owns property (whether fee-owned property or other property right, such as a right to flood) in or adjacent to the reach (including property adjacent to a TVA reservoir or downstream of a TVA dam).

TVA *will* continue to review the proposed construction of obstructions located across, along, or in the above-listed five categories of reservoirs and reaches. These reservoirs and stream reaches are controlled or influenced by the operation of TVA's reservoir system. As discussed in more detail below, individual members of the public are encouraged to contact a TVA representative for help in determining whether their location is across, along, or in a reservoir or stream reach in the above-listed five categories or across, along, or in an upstream tributary reach.

III. Scope of Interpretive Rule

TVA hereby clarifies that, going forward, the construction of the following obstructions across, along, or in an upstream tributary reach of the Tennessee River, does not require a Section 26a permit from TVA:

(a) Stream bank, bed, or channel stabilization structures—Natural or man-made obstructions to stabilize and protect banks, beds, or channels of streams or excavated channels (*e.g.*, vegetation, riprap, gabions, fiber rolls, stacked rock, retaining walls, etc.);

(b) Stream restoration, enhancement, relocation, or treatment structures—Natural or man-made obstructions for relocating a stream or for restoring or improving the stream's function (*e.g.*, weirs or sills, boulders, wing deflectors, log, brush, rock, trees, fill, etc.);

(c) Bridges and culverts including riprap or other stabilization necessary for their construction;

(d) Stream crossings—A stabilized area or a structure (culvert, bridge, or fill) constructed across a stream to provide a travel-way for people, livestock, equipment, or vehicles, including riprap or other stabilization necessary for their construction;

(e) Fences, playgrounds, picnic tables, benches, grills, and other recreational structures;

(f) Launching ramps and marine railways;

(g) Buoys;

(h) Docks, piers, and other water-use facilities;

(i) Decks, gazebos, patios, and other open structures;

(j) Enclosed land-based structures;

(k) Water intakes with a combined peak withdrawal of less than 50,000 gallons per day (0.08 cubic feet per second) and having a pipe diameter less than 6 inches;

(l) Towers, poles, electrical panels, satellite antennas, service lights, signs, and their anchors and foundations;

(m) Outfall structures;

(n) Underground, submarine, or aerial utility pipes and lines and their support structures, anchors or foundations;

(o) Causeways, roads, driveways, and parking lots;

(p) Grading and fill not involving the construction of a dam or impoundment.

Those considering construction of one or more of the above-listed obstructions across, along, or in an upstream tributary reach as defined in this rule are not required to submit an application or design drawings to TVA for approval of a Section 26a permit.

Members of the public are responsible for knowing whether their proposed construction project is located across, along, or in an upstream tributary reach or on TVA property. If your proposed obstruction is located on TVA property, in addition to a Section 26a permit for the obstruction, approval from TVA to use the property may be required. TVA encourages members of the public to seek TVA's help in identifying whether a Section 26a permit or TVA approval to use its property is necessary. For more information or assistance in determining whether your project requires a Section 26a permit, contact TVA at 1–800–882–5263 or visit TVA's Web site at tva.com.

Except as it applies to TVA's regulations implementing Section 26a, this interpretive rule is not a substitute for the requirements of any federal, state, or local statute, regulation, ordinance, or code, including, but not limited to, applicable building codes, now in effect or hereafter enacted.

This guidance reflects TVA's current judgment on the types of obstructions that either individually or cumulatively do not affect navigation, flood control, or public lands or reservations across, along, or in an upstream tributary reach of the Tennessee River. TVA may refine this guidance, if circumstances warrant, in a future **Federal Register** notice. This guidance has no effect on whether a permit is required by other federal or state agencies.

IV. Definitions

Fee-owned property—Real property owned in fee by the United States of America in the custody and control of TVA.

Property—Fee-owned property or other property right, such as a right to flood.

Property right—Any legal right acquired or reserved by TVA that concerns property, such as a right to flood private property.

Reach—A segment of stream between two locations.

Tennessee River—The river reach from its mouth at the Ohio River to its beginning at mile 652, at the confluence of the Holston and French Broad Rivers.

Tributary—Any watercourse the contents of which, if not obstructed, diverted or consumed, will ultimately flow into the Tennessee River.

TVA reservoir—The impoundment created by a TVA dam constructed across the Tennessee River or one of its tributaries (including all streams reaches impounded by the dam). One dam may impound reaches of more than one stream. The impounded stream reaches together form the body of water (*i.e.,* the reservoir) created by the construction of the dam. For example, the construction of Douglas Dam impounded a portion of the French Broad River as well as many other stream reaches, including, but not limited to, portions of Pigeon River, Nolichucky River, Flat Creek, Muddy Creek, and Seahorn Creek. All of the stream reaches impounded by Douglas Dam comprise Douglas Reservoir.

TVA reservoir system—The series of interconnected dams and reservoirs, with associated facilities, on the Tennessee River and its tributaries, that, with the adjacent TVA property, are managed by TVA for purposes of navigation, flood control, and power production; and consistent with those purposes, for a wide range of other public benefits.

Upstream tributary reach—Stream reaches located upstream of the control or influence of the operation of the TVA reservoir system.

Dated: August 17, 2016.

Rebecca C. Tolene,

Deputy General Counsel and Vice President, Natural Resources.

TABLE 1—TVA RESERVOIRS

Tennessee River Reservoirs	
Kentucky. Pickwick. Wilson. Wheeler. Guntersville. Nickajack. Chickamauga. Watts Bar. Fort Loudoun.	
Tributary Reservoirs	
Apalachia. Beaver Creek (tributary to South Fork Holston River). Blue Ridge. Boone. Chatuge. Cherokee. Clear Creek (tributary to Beaver Creek, tributary to South Fork Holston River). Doakes Creek (Norris Reservoir).	*Bear Creek Projects (Alabama):* Bear Creek. Cedar Creek. Little Bear Creek. Upper Bear Creek. *Beech River Projects (West Tennessee):* Beech. Cedar. Dogwood. Lost Creek.

TABLE 1—TVA RESERVOIRS—Continued

Douglas.
Fontana.
Fort Patrick Henry.
Hiwassee.
John Sevier Detention Dam (just upstream of Cherokee Reservoir).
Melton Hill.
Nolichucky.
Normandy.
Norris.
Nottely.
Ocoee No. 1.
Ocoee No. 2.
Ocoee No. 3.
South Holston.
Tellico.
Tims Ford.
Watauga.
Wilbur.
Pine.
Pin Oak.
Redbud.
Sycamore.

TABLE 2—STREAM REACHES DOWNSTREAM OF TVA DAMS

River or stream	Reach (mile)	Description
Tennessee River	0 to 652	Mouth to confluence of the Holston and French Broad Rivers.
Beaver Creek (tributary to South Fork Holston River)	0 to 22.5	Mouth to Beaver Creek Dam.
Clear Creek (tributary to Beaver Creek tributary to South Fork Holston River).	0 to 2.8	Mouth to Clear Creek Dam.
Clinch River	0 to 79.8	Mouth to Norris Dam.
Duck River	0 to 248.6	Mouth to Normandy Dam.
Elk River (tributary to Tennessee River)	0 to 133.3	Mouth to Tims Ford Dam.
French Broad River	0 to 32.3	Mouth to Douglas Dam.
Hiwassee River	0 to 121.0	Mouth to Chatuge Dam.
Holston River	0 to 142.2	Mouth to confluence of the North and South Fork Holston Rivers.
Little Tennessee River [1]	0 to 61.0	Mouth to Fontana Dam.
Nolichucky River	0 to 45.6	Mouth to Nolichucky Dam.
Nottely River	0 to 21.0	Mouth to Nottely Dam.
Ocoee River	0 to 37.8	Mouth to the Georgia/Tennessee State Line.
South Fork Holston River	0 to 49.8	Mouth to South Holston Dam.
Toccoa River	0 to 53.0	The Georgia/Tennessee State Line to Blue Ridge Dam.
Watauga River	0 to 36.7	Mouth to Watauga Dam.
Bear Creek Projects (Alabama):		
Bear Creek	0 to 114.7	Mouth to Upper Bear Creek Dam.
Cedar Creek	0 to 23.1	Mouth to Cedar Creek Dam.
Little Bear Creek	0 to 11.6	Mouth to Little Bear Creek Dam.
Beech River Projects (West Tennessee):		
Beech River	0 to 35.0	Mouth to Beech Dam.
Big Creek	0 to 6.7	Mouth to Dogwood Dam.
Browns Creek	0 to 5.1	Mouth to Pin Oak Dam.
Dry Branch	0 to 1.1	Mouth to Sycamore Dam.
Dry Creek	0 to 1.0	Mouth to Redbud Dam.
Haley Creek	0 to 4.0	Mouth to Cedar Dam.
Lost Creek	0 to 1.3	Mouth to Lost Creek Dam.
Piney Creek	0 to 4.8	Mouth to Pine Dam.

[1] Brookfield Smoky Mountain Hydro manages Little Tennessee River Miles 33.6 to 59.1.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9784]

RIN 1545–BM05

Definition of Real Estate Investment Trust Real Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that clarify the definition of real property for purposes of the real estate investment trust provisions of the Internal Revenue Code (Code). These final regulations provide guidance to real estate investment trusts and their shareholders.

DATES: *Effective date:* These regulations are effective on August 31, 2016.

Applicability date: For dates of applicability, see § 1.856–10(h).

FOR FURTHER INFORMATION CONTACT: Julanne Allen of the Office of Associate Chief Counsel (Financial Institutions and Products) at (202) 317–6945 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) relating to real estate investment trusts (REITs). Section 856 of the Code defines a REIT by setting forth various requirements. One of the requirements for a taxpayer to qualify as a REIT is that at the close of each quarter of the taxable year at least 75 percent of the value of its total assets is represented by real estate assets, cash and cash items (including receivables), and Government securities. See section 856(c)(4). Section 856(c)(5)(B) defines *real estate assets* to include real property (including interests in real property and interests in mortgages on real property). Section 856(c)(5)(C) defines *interests in real property* to include fee ownership and co-ownership of "land or improvements thereon." Prior to these final regulations, § 1.856–3(d) of the Income Tax Regulations, promulgated in 1962 in TD 6598 (the 1962 Regulations), defined real property for purposes of the regulations under sections 856 through 859. Under § 1.856–3(d) of the 1962 Regulations, the term *real property means* land or improvements thereon, such as buildings or other inherently permanent structures thereon (including items which are structural components of such buildings or structures). In addition, the term "real property" includes interests in real property. Local law definitions will not be controlling for purposes of determining the meaning of the term "real property" as used in section 856 and the regulations thereunder. The term includes, for example, the wiring in a building, plumbing systems, central heating, or central air-conditioning machinery, pipes or ducts, elevators or escalators installed in the building, or other items which are structural components of a building or other permanent structure. The term does not include assets accessory to the operation of a business, such as machinery, printing press, transportation equipment which is not a structural component of the building, office equipment, refrigerators, individual air-conditioning units, grocery counters, furnishings of a motel, hotel, or office building, etc., even though such items may be termed fixtures under local law.

The IRS issued revenue rulings between 1969 and 1975 addressing whether certain assets qualify as real property for purposes of section 856. Specifically, the published rulings address whether assets such as railroad properties,[1] mobile home units permanently installed in a planned community,[2] air rights over real property,[3] interests in mortgage loans secured by total energy systems,[4] and mortgage loans secured by microwave transmission property[5] qualify as either real property or interests in real property under section 856. After these published rulings were issued, REITs invested in various types of assets that are not directly addressed by the regulations or the published rulings, and some of these REITs received letter rulings from the IRS concluding that certain of these various assets qualified as real property. A letter ruling, however, may not be relied upon by taxpayers other than the taxpayer that received the letter ruling[6] and is limited to its particular facts. The Treasury Department and the IRS recognized the need to provide updated published guidance on the definition of real property under sections 856 through 859. On May 14, 2014, the Treasury Department and the IRS published in the **Federal Register** a notice of proposed rulemaking (REG–150760–13 at 79 FR 27508) (NPRM) to define "real property" solely for purposes of sections 856 through 859 and provisions that reference the definition of real property in section 856 and the regulations thereunder.

Written and electronic comments responding to the NPRM were received. The written comments are available for public inspection at *http://www.regulations.gov* or upon request. A public hearing was held on September 18, 2014.

After consideration of all the comments, these final regulations adopt the proposed regulations as revised by this Treasury decision.[7] The comments and revisions are discussed in this preamble.

Summary of Comments and Explanation of Revisions

I. The Definition of Land

The proposed regulations defined the term "land" to include water and air space superjacent to land and natural products and deposits that are unsevered from the land. A commenter requested clarification that land includes water space and air space above ground that the taxpayer does not own. For example, a taxpayer may own a building and purchase air rights superjacent to one or more neighboring buildings to enhance the value of the building the taxpayer owns, or a taxpayer may purchase air rights in anticipation of using those rights to facilitate the future acquisition or development of property. The Treasury Department and the IRS agree that air space or water space superjacent to land each qualify as land even if the taxpayer owns only the air space or water space and does not own an interest in the underlying land. The proposed regulations stated that superjacent water and air space qualify as land, and these final regulations retain the language of the proposed regulations.

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[1] Rev. Rul. 69–94 (1969–1 CB 189).

[2] Rev. Rul. 71–220 (1971–1 CB 210).

[3] Rev. Rul. 71–286 (1971–2 CB 263).

[4] Rev. Rul. 73–425 (1973–2 CB 222).

[5] Rev. Rul. 75–424 (1975–2 CB 269).

[6] Rev. Proc. 2016–1 (2016–1 IRB 1), section 11.02; see section 6110(k)(3) of the Code.

[7] Under section 856(c)(2) and (3), in order for an entity to qualify as a REIT, certain prescribed percentages of that entity's gross income must be derived from certain types of income (which include "rents from real property" and "interest on obligations secured by mortgages on real property or on interests in real property"). The definition of real property in these final regulations applies for purposes of section 856(c)(2) and (3), but these final regulations provide neither explicit nor implicit guidance regarding whether various types of income are described in section 856(c)(2) and (3).

II. The Definition of Improvements to Land

The proposed regulations generally defined the term "improvements to land" to mean inherently permanent structures (IPSs) and their structural components. A commenter recommended that these final regulations clarify that clearing, grading, landscaping, and earthen dams should be treated as improvements to land. The Treasury Department and the IRS believe that, to the extent these assets are distinct assets that have value apart from the land, the REIT must analyze these assets separately under these final regulations. For example, if landscaping includes shrubs planted in the ground, the shrubs are within the definition of land in these final regulations so long as the shrubs remain unsevered natural products of the land. If, however, landscaping includes a bench that is a distinct asset, the bench is analyzed under the factors for an IPS in these final regulations to determine whether the bench is real property.

III. The Definition of IPS

A. Passive Function Requirement and Active Function Prohibition

1. In General

Under the proposed regulations, IPSs include buildings and other inherently permanent structures (OIPSs). To qualify as an OIPS under the proposed regulations, a structure must serve a passive function, such as contain, support, shelter, cover, or protect, and not serve an active function, such as manufacture, create, produce, convert, or transport. Commenters suggested that use of the terms active and passive may cause confusion because, for example, REITs may be engaged in the active conduct of a trade or business within the meaning of section 355(b) solely by virtue of functions with respect to rental activity that produce income qualifying as rents from real property within the meaning of section 856(d).[8]

During the hearing, a commenter stated that REITs may perform certain services and that the requirement that an IPS serve a passive function may be at odds with this permissible activity. This commenter suggested that the requirement be revised to: (1) State that OIPSs serve a real estate-related function; (2) require that the asset not primarily contribute to the production of income other than for the use, occupancy, or financing of space; or (3) not include the terms passive and active when describing permissible and prohibited functions. Other commenters suggested that the function of a distinct asset not be considered in determining whether the distinct asset is an OIPS. These commenters maintained that inherent permanence should be the only requirement for a distinct asset to qualify as an OIPS.

These final regulations do not adopt these suggestions. These final regulations address whether the asset itself has a passive function, not whether the asset is used in an active trade or business or whether income from the asset is income from an active trade or business. The requirement in the proposed regulations and in these final regulations that an asset serve a passive function is intended to be a more precise statement of the distinction previously set forth in § 1.856–3(d) of the 1962 Regulations, which treated as real property certain passive assets but not assets accessory to the operation of a business, including machinery. The Treasury Department and the IRS believe that the terms passive and active, when taken together with the examples in these final regulations, appropriately clarify and illustrate the permissible functions of an OIPS. The passive function requirement neither prohibits a tenant from using a passive asset, such as an office building, in the tenant's active business nor limits a REIT's ability to perform either the services excepted under section 856(d)(7)(C)(ii) or the trustee or director functions permitted by § 1.856–4(b)(5)(ii).

The Treasury Department and the IRS believe that the commenters' suggested real estate-related standard is circular and might support real property treatment for assets that serve active functions. Further, the Treasury Department and the IRS do not agree that inherent permanence alone is a sufficient basis for a distinct asset to be treated as an IPS. For example, the Treasury Department and the IRS continue to believe that some inherently permanent assets, such as large, heavy machinery, do not qualify as real property for purposes of section 856.

A commenter suggested replacing the passive function requirement with a test that focuses on an asset's human factor, which the commenter defined as whether, and the extent to which, human involvement is needed for an asset to function. This commenter contended that human involvement is a characteristic of an active function and, therefore, should be taken into account in determining whether a particular asset is active or passive. The Treasury Department and the IRS disagree and continue to believe that machinery, including automated machinery that functions with little or no human involvement, does not qualify as real property for purposes of section 856.

2. Transport as a Prohibited Active Function

The proposed regulations listed transport as an active function. Commenters noted that this active function differs from the other four active functions (manufacture, create, produce, and convert) that involve changing the physical nature or character of a commodity or good. Commenters also suggested that some of the assets on the list of types of OIPSs in the proposed regulations, such as railroad tracks and tunnels, help to transport a good or a commodity.[9]

The Treasury Department and the IRS agree that the term transport could be interpreted to describe functions of both passive conduits used for transportation and machines that push or pull items through or along a conduit. The Treasury Department and the IRS intend the term transport to mean to cause to move, and these final regulations retain transport as a prohibited active function of an OIPS. To provide clarity, these final regulations include providing a conduit (such as in the case of a pipeline or electrical wire) or route (as in the case of a road or railroad track) as a permitted passive function of an OIPS.

3. Assets With Both Active and Passive Functions

In addition to other requirements, § 1.856–10(d)(2)(i) of the proposed regulations stated that a distinct asset that serves an active function, such as machinery or equipment, is not a building or OIPS.

Commenters suggested that solar panels can perform dual functions, including a passive function (that is, to shelter) and an active function (that is, to convert (energy)). Commenters stated that solar panels may be used to protect pastures, parking lots, buildings, and other structures from the detrimental effects of solar radiation and to manage temperature through shading. The structures to which solar panels are attached—or even into which they are integrated—may qualify as IPSs under the proposed regulations.

The Treasury Department and the IRS note that the example given by the commenters presumes that the solar panel structure is a single distinct asset that serves a passive function of sheltering and an active function of converting energy for sale to third parties. If this were the case, the solar panel structure would fail to qualify as an IPS under § 1.856–10(d)(2)(i) of the proposed regulations as a result of the structure's active function. If, however, a solar panel structure is composed of multiple distinct assets, then each of those distinct assets would be analyzed under the proposed regulations to determine whether it qualifies as an IPS or as a structural component of an IPS.[10] Because these final regulations retain the requirement that an IPS not serve an active function, machinery and equipment that may serve both passive and active functions are excluded from the definition of an IPS.

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[8] See Rev. Rul. 2001–29 (2001–1 CB 1348).

[9] Commenters also noted that several assets listed as structural components, such as elevators and escalators, transport objects or occupants of a building. A structural component may have an active function if the structural component serves the passive function of the IPS of which it is constituent.

B. Definition of Building

Section 1.856–10(d)(2)(ii)(A) of the proposed regulations stated that a building encloses a space within its walls and is covered by a roof. Examples given in § 1.856–10(d)(2)(ii)(B) of the proposed regulations were permanently affixed houses, apartments, hotels, factory and office buildings, warehouses, barns, enclosed garages, enclosed transportation stations and terminals, and stores.

During the hearing, a commenter stated that for appraisal purposes, buildings are considered to be buildings regardless of their permanence. This commenter suggested that these final regulations should adopt standards published by an appraisal organization to define real property.

Section 1.856–3(d) of the 1962 Regulations indicates that inherent permanence is important in determining whether a structure qualifies as real property. A tent, for example, may satisfy the portion of the definition of a building in the proposed regulations that referenced enclosing within its walls a space that is covered by a "roof," but the impermanent nature of the tent would prevent it from qualifying as a building for purposes of section 856. The purposes of definitions used by appraisal organizations, which focus on valuation, differ from the purposes of definitions used for REIT qualification purposes. For example, although both permanent and impermanent property may be appraised, permanence is of crucial importance in defining real property for REIT qualification purposes. Therefore, these final regulations do not adopt standards published by an appraisal organization.

Another commenter urged the Treasury Department and the IRS to change the definition of building in these final regulations so that the definition does not depend on whether a space is completely enclosed by its walls and covered by a roof. The commenter stated that even an outdoor sports stadium or amphitheater and an unenclosed parking garage that are permanently affixed to land or another IPS may fail to qualify as buildings under the proposed regulations.

The Treasury Department and the IRS agree that these structures may fail to meet the definition of building under the proposed regulations. The Treasury Department and the IRS believe, however, that many outdoor sports stadiums, amphitheaters, and unenclosed parking garages would satisfy the definition of an OIPS in § 1.856–10(d)(2)(iii) of the proposed regulations and that this definition is more appropriate for these structures. Therefore, the definition of building in the proposed regulations is retained in these final regulations.

C. Clarification of the Term Indefinitely

The proposed regulations stated that, to qualify as an IPS, a distinct asset must be permanently affixed and that if the affixation is reasonably expected to last indefinitely based on all the facts and circumstances, the affixation is considered permanent.

Commenters indicated that the term indefinitely as used in determining whether an asset is an IPS was unclear. A commenter suggested using an asset's useful life as an alternate to indefinitely. The Treasury Department and the IRS have concluded that relying on the useful life of an asset as the measure for permanence would have the effect of treating certain impermanent assets as real property. For example, if an asset has a useful life of two years, it would be inappropriate for the asset to be treated as permanently affixed solely because the asset was reasonably expected to remain in place for two years.

Another commenter provided the example of a REIT that constructs a building on land on which the REIT holds a 99-year ground lease. Upon expiration of the lease, the building is subject to removal. In this case, the building may not be on the land in 100 years. Another commenter provided the example of a building that is subject to condemnation and that will be torn down in the future.

Another commenter suggested that whether an asset is inherently permanent should be based upon an objective analysis of the physical nature of the manner of affixation, rather than on a particular taxpayer's subjective intent. This commenter recommended that if the manner of affixation is of a permanent nature and is consistent with the distinct asset remaining in place indefinitely based on all the facts and circumstances, the affixation is considered permanent. Commenters also urged the Treasury Department and the IRS to provide a statement in the preamble to these final regulations that indefinitely does not mean forever but rather means for the foreseeable future.

The Treasury Department and the IRS do not intend the term indefinitely to mean forever. The proposed regulations stated that whether affixation is reasonably expected to last indefinitely is based on all the facts and circumstances. Section 1.856–10(d)(2)(iv) provides factors that must be taken into account to determine whether a distinct asset is an IPS if that distinct asset is not included in the lists of types of buildings in § 1.856–10(d)(2)(ii)(B) or types of OIPSs in § 1.856–10(d)(2)(iii)(B). These factors provide additional guidance on the meaning of permanent affixation. The primary focus of these factors is on the nature of the distinct asset and the affixation, including the manner in which the distinct asset is affixed, whether the distinct asset is designed to be removed, the damage that removal would cause, and the time and expense required to move the distinct asset. Although one factor includes any circumstances that suggest the expected period of affixation is not indefinite and provides as an example a lease that requires or permits removal of the distinct asset upon the expiration of the lease, the determination of whether a distinct asset is an IPS is based on all of the facts and circumstances.

These final regulations do not adopt these suggestions and, because the Treasury Department and the IRS do not believe additional guidance regarding inherent permanence is necessary, retain the definition of IPS as proposed.

D. Suggested Presumption for Structures With a Certificate of Occupancy or Similar License

A commenter agreed that state or local definitions of property should not control for purposes of the definition of real property under section 856, but suggested that when a certificate of occupancy or similar license or certification is granted with respect to a structure, the structure be presumed to constitute real property for purposes of section 856 unless the facts and circumstances clearly indicate that the structure is not permanent.

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[10] A similar analysis was applied to the solar energy site assets in § 1.856–10(g), *Example 8,* of the proposed regulations.

Local law standards for a certificate of occupancy or similar license or certification might be inconsistent with the definition of real property for purposes of section 856. For example, local law might permit issuance of a certificate of occupancy for a tent that is not inherently permanent. In addition, this presumption might lead to inconsistent results. For example, two identical assets located in localities that use different standards for licensing might be treated differently for purposes of section 856 because a certificate of occupancy has been granted to one of the assets and not to the other. For these reasons, we believe the suggested presumption would create confusion and administrative difficulty, and, therefore, these final regulations do not adopt this comment.

IV. The Definition of Structural Component

A. Income Produced by a Structural Component

In generally defining the term structural component, § 1.856–10(d)(3)(i) of the proposed regulations stated, in part, that a structural component is any distinct asset that is a constituent part of and integrated into an IPS, serves the IPS in its passive function, and, even if capable of producing income other than consideration for the use or occupancy of space, does not produce or contribute to the production of such income.

A commenter requested that the words ''and related services'' be added to the language of § 1.856–10(d)(3)(i). If that request were adopted, structural components would include assets that serve the IPS and even if capable of producing income other than consideration for the use or occupancy of space *and related services,* do not produce or contribute to the production of such income (emphasis added to indicate commenter's suggested language). The commenter stated that REITs use property such as the systems that supply utilities to a building to provide services to tenants. The commenter explained that a REIT may receive additional compensation to cover utilities that the REIT provides to the tenant when the tenant uses space in the building outside of specified business hours.

The Treasury Department and the IRS have concluded that the definition of structural component in the proposed regulations adequately accounts for the concerns raised by the commenter, and accordingly these final regulations do not incorporate the commenter's suggested revision.

B. Proposed Utility Safe Harbor for Structural Components

A commenter recommended that these final regulations adopt a safe harbor for distinct assets that provide utilities to IPSs. The commenter recognized that the utility-like function aspect of the definition in the proposed regulations underscores the importance of that type of structural component and suggested that a distinct asset that serves a utility-like function with respect to an IPS should be conclusively presumed to be a structural component of that IPS.

The Treasury Department and the IRS note that the list of types of structural components in the proposed regulations included several utility-like systems, such as plumbing systems, central heating and air-conditioning systems, fire suppression systems, central refrigeration systems, and humidity control systems. The Treasury Department and the IRS may add other systems that satisfy the factors in § 1.856–10(d)(3)(iii) to the structural component list through future guidance published in the Internal Revenue Bulletin. The proposed regulations differentiated systems that perform utility-like functions from other distinct assets to permit analysis of these systems as a whole. Under the proposed regulations, once it has been determined that an asset or assets function as a utility-like system, the system is analyzed as a distinct asset basing the determination of whether the system is real property on all of the facts and circumstances and using the factors listed under § 1.856–10(d)(3)(iii) for structural components. A system or asset that provides a utility but that does not qualify as a structural component under the facts and circumstances test under § 1.856–10(d)(3)(iii) (for example, a window air-conditioning unit) is not a structural component.

Because the Treasury Department and the IRS believe that the factors listed under § 1.856–10(d)(3)(iii) for structural components are important to the analysis of systems that provide a utility-like function these final regulations decline to adopt the blanket rule suggested by the commenter.

C. The Equivalent Interest Requirement for Structural Components

Section 1.856–10(d)(3)(i) of the proposed regulations stated that a distinct asset is a structural component if the interest held therein is included with an equivalent interest held by the taxpayer in the IPS to which the structural component is functionally related. Commenters suggested that the equivalent interest requirement for structural components be deleted or amended because the requirement: (1) Is inconsistent with industry practices and an asset should qualify as a structural component even if the REIT owns the asset but leases from another party the building served by the structural component; (2) may negatively affect investment in energy efficient and renewable energy assets; (3) was not explained in the proposed regulations and seemingly serves no tax policy purpose; and (4) is contrary to congressional intent, case law, and the treatment of structural components by the IRS in other contexts.

The Treasury Department and the IRS intended that the equivalent interest requirement in the proposed regulations ensure that an asset did not qualify as a structural component unless that asset served real property in which the REIT also had an interest. The Treasury Department and the IRS set forth a similar requirement in Rev. Rul. 73–425, which addresses notes secured by a total energy system. Rev. Rul. 73–425 holds that obligations secured by a mortgage covering a total energy system and the building that the system served qualify as real estate assets. The revenue ruling also holds that an obligation secured only by the total energy system does not qualify as a real estate asset.

The Treasury Department and the IRS believe that, to treat an asset as a structural component, a REIT must hold its interest in the structural component together with a real property interest with respect to the space in the IPS that the structural component serves. For example, a central air-conditioning system is a machine that does not separately qualify as an IPS. A central air-conditioning system that is wholly owned by a REIT may, however, qualify as a structural component if the REIT also holds a real property interest, such as a leasehold interest, with respect to the space in the IPS served by the central air-conditioning system. Limiting the definition of structural component to assets that serve an IPS in which the REIT has a real property interest is consistent with the statutory requirement that REITs invest in real property or interests in real property.

For these reasons, these final regulations provide that a distinct asset qualifies as a structural component only if the REIT holds its interest in the distinct asset together with a real property interest with respect to the space in the IPS that the distinct asset serves. In addition, as illustrated by Rev.

Rul. 73–425, for a mortgage that is secured by a structural component to qualify as a real estate asset under these final regulations, the mortgage also must be secured by the IPS served by the structural component.

D. Suggested Standard for Structural Components

Section 1.856–10(3)(i) of the proposed regulations defined a structural component to include a distinct asset that serves the IPS in its passive function, and, even if capable of producing income other than consideration for the use or occupancy of space, does not produce or contribute to the production of such income. Section 1.856–10(d)(3)(ii) of the proposed regulations furnished a list of distinct assets that are structural components. The proposed regulations also stated that a distinct asset that was not on this list might still be a structural component based on all of the facts and circumstances. In particular, the proposed regulations required the factors listed under § 1.856–10(d)(3)(iii) to be taken into account.

A commenter suggested that the standard for a structural component should be revised so that a structural component is defined as a distinct asset that is intended to protect, preserve, secure, or support the safe operation of the IPS. The commenter suggested that satisfying this standard should be sufficient to determine if a distinct asset is a structural component and, therefore, the structural component factor test under § 1.856–10(d)(3)(iii) of the proposed regulations is unnecessary.

These final regulations do not adopt the commenter's suggestion because the standard suggested would in some circumstances unduly limit the functions a structural component may serve and in other circumstances unduly expand the functions a structural component may serve. The Treasury Department and the IRS do not believe this modification is necessary given these final regulations' requirement that a structural component serve the IPS to which the structural component is constituent in the IPS's passive function. In addition, the Treasury Department and the IRS have concluded that adopting a standard that takes into account a taxpayer's intent regarding an asset may lead to inconsistent results because different taxpayers may have different intentions regarding the same type of distinct asset.

V. Requested Additions to the Lists of Qualifying Assets

A. General Suggestions

Sections 1.856–10(d)(2)(ii)(B), 1.856–10(d)(2)(iii)(B), and 1.856–10(d)(3)(ii) of the proposed regulations furnished lists of types of distinct assets that would qualify as buildings, OIPSs, and structural components, respectively. A commenter requested that certain other distinct assets be included on these lists. These other distinct assets included car charging stations, healthcare facilities, storage facilities, timber, electrical distribution and redundancy systems, telecommunication systems, and equipment comprising a building management system.

The Treasury Department and the IRS have considered the proposed additions to the lists of qualifying assets and believe that the proposed regulations already addressed the tax treatment of certain of these assets, such as storage facilities and timber. In addition, the Treasury Department and the IRS are not persuaded that the other assets will in all cases satisfy the relevant definition. Therefore, these final regulations do not include these suggested additions to the lists of qualifying assets.

B. Additions to the Lists for Types of IPSs

1. Additions to the List for Types of Buildings

Commenters suggested adding motels, casinos, health care facilities, storage facilities, greenhouses, enclosed stadiums, enclosed shopping malls, museums, municipal buildings, other housing (such as assisted living), parking garages (whether or not fully enclosed), and mixed-use properties combining one or more of the foregoing to the list for buildings under § 1.856–10(d)(2)(ii)(B) of the proposed regulations.

These assets would not always qualify as buildings as defined under the proposed regulations and in these final regulations. For example, casinos may be on an unaffixed barge or riverboat, health care facilities may be in tents, storage facilities may include movable pods, and greenhouses may be structures that are not permanently affixed. Unenclosed parking garages were not within the definition of a building under the proposed regulations but were included in the list of types of OIPSs in § 1.856–10(d)(2)(iii)(B) of the proposed regulations (which included permanently affixed parking facilities). Museums may exist on unaffixed boats, in a room inside a building, or in the open air.

A mixed-use building would still qualify as a building because it encloses space within its walls and is covered by a roof. On the other hand, a mixed-use property comprised of several structures would require a separate analysis of each structure. The suggestions to include municipal buildings and assisted-living facilities focus on the use, rather than the type, of structure. In addition, office buildings, apartments, and houses were already included on the proposed regulations' list.

A distinct asset not on the list may nevertheless qualify as a building, because the list for types of buildings in the proposed regulations is not exclusive. Moreover, many of the requested assets are already included in that list. For these reasons, these final regulations do not include all the requested assets on the list for types of buildings. However, these final regulations include as types of buildings permanently affixed motels, enclosed stadiums and arenas, and enclosed shopping malls.

2. Additions to the List for Types of OIPSs

Some commenters requested certain assets be added to the list under § 1.856–10(d)(2)(iii)(B) of the proposed regulations for types of OIPSs, including energy storage components, solar photovoltaic (PV) panels, related wiring and functionally related transformers, power conditioning equipment, and electrical power inverters and related wiring.

The Treasury Department and the IRS have determined that adding these assets to the list for types of OIPSs is not warranted. Inclusion of these assets would be inconsistent with the requirements that OIPSs serve a passive function and do not serve an active function.[11] Therefore, these final regulations do not include these assets on the list for types of OIPSs.

C. Additions to the List for Types of Structural Components

One commenter suggested that the list under § 1.856–10(d)(3)(ii) of the proposed regulations for types of structural components should include special flooring for data centers. The proposed regulations stated that customization of a distinct asset in connection with the rental of space in or on an IPS to which the distinct asset relates does not affect whether the distinct asset qualifies as a structural component. The list of types of structural components in § 1.856–10(d)(3)(ii) of the proposed regulations included permanent coverings of floors. The commenter's suggestion of specifically including special flooring in a data center is an example of customization of a distinct asset in connection with the rental of space in an IPS. These final regulations, like the proposed regulations, permit the customization of distinct assets in connection with the rental of space in or on an IPS, provided that the customized asset is integrated into the IPS and is held together with a real property interest in the space in the IPS that is served by the asset. Accordingly, these final regulations do not include special flooring in a data center on the list of types of structural components.

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[11] Depending on all the facts and circumstances, however, some or all of these assets may qualify as structural components of an IPS.

Another commenter recommended that the list for types of structural components be expanded to include solar energy generating and heating systems and related energy storage equipment. The Treasury Department and the IRS do not believe that solar energy generating and heating systems and related energy storage equipment necessarily satisfy the definition of structural components in § 1.856–10(d)(3) of the proposed regulations but rather believe these assets should be analyzed using all the facts and circumstances and taking into account the factors provided in § 1.856–10(d)(3)(iii) of these final regulations. For these reasons, these final regulations do not adopt the recommendation.

VI. Recommended Changes to the Factor Lists in § 1.856–10(d)(2)(iii) and (3)(iv) of the Proposed Regulations

A. Recommended Change to the Factors Used To Determine Whether a Distinct Asset Is an IPS

The proposed regulations listed factors to be considered in determining whether a distinct asset (other than a type of building or type of OIPS listed in § 1.856–10(d)(2)(ii)(B) of the proposed regulations or § 1.856–10(d)(2)(iii)(B) of the proposed regulations, respectively) is an IPS. One factor is whether there are any circumstances that suggest the expected period of affixation is not indefinite (for example, a lease that requires or permits removal of the distinct asset upon the expiration of the lease).

One commenter stated that buildings constructed on land subject to a long-term ground lease arguably would not satisfy this factor. Another commenter stated that removal provisions are common in commercial leases and, as a practical matter, such provisions may not be determinative as to whether the asset is ultimately removed by the lessee at the expiration of the lease. This commenter recommended that the factor be changed to any circumstance that suggests the manner of affixation is temporary in nature rather than permanent.

As previously discussed in this preamble, for purposes of section 856, the Treasury Department and the IRS do not intend the term indefinitely to mean forever. Whether a distinct asset qualifies as an IPS depends on all the facts and circumstances including an analysis of the factors in § 1.856–10(d)(2)(iv). For these reasons, this factor is not modified in these final regulations.

B. Recommended Change to the Factors Used To Determine Whether a Distinct Asset Is a Structural Component

For distinct assets other than those listed in § 1.856–10(d)(3)(ii) of the proposed regulations as structural components, the proposed regulations listed factors under § 1.856–10(d)(3)(iii) that must be taken into account in determining whether the distinct asset qualifies as a structural component of an IPS. One of those factors was whether the owner of the property was also the legal owner of the distinct asset. A commenter noted that a REIT may have a leasehold interest in real property and may own a structural component that it installs as part of the real property. An example provided by the commenter is a REIT that leases the shell of a building and then engages independent contractors to complete internal build-outs to customize the shell of the building into a shopping mall.

The Treasury Department and the IRS have considered this comment, along with the comments received regarding the equivalent interest requirement, as discussed in this preamble. Accordingly, these final regulations require that, for a distinct asset to be a structural component, a REIT must hold a legally enforceable real property interest in the space in the IPS that the structural component serves.

VII. Intangible Assets

A. Intangibles Derived From the Trade or Business of Earning Revenues for the Use of Real Property or Related Services

Under § 1.856–10(f) of the proposed regulations, an intangible asset is real property or an interest in real property if the asset derives its value from real property or an interest in real property, is inseparable from that real property or interest in real property, and does not produce or contribute to the production of income other than consideration for the use or occupancy of space. Commenters requested inclusion of intangible assets derived from services that produce income other than consideration for the use or occupancy of space, which would include workforce-in-place and customer-based intangibles. The Treasury Department and the IRS believe that intangible assets that are separable from real property or an interest in real property should not qualify as real property. The final regulations clarify that intangible assets that are related to services and that are separable from the real property do not qualify as real property.

B. In-Place Above and Below-Market Leases

Commenters requested that intangible assets related to in-place above-market leases in which the REIT is the lessor and below-market leases in which the REIT is the lessee be treated as qualifying real property. Under section 856(c)(5)(C), a lease of land or improvements thereon is an interest in real property and, therefore, a lease of land or improvements thereon is a real estate asset under section 856(c)(5)(B). A lease of real property that produces both rents from real property under section 856(d)(1) and other income that does not so qualify is, in part, an interest in real property under section 856(c)(5)(C) and, in part, an asset other than an interest in real property. To the extent the portion of the lease that is an interest in real property has value, that portion is a real estate asset under section 856(c)(5)(B). These final regulations have been modified to clarify that an intangible asset may be, in part, an interest in real property and, in part, an asset other than an interest in real property. In addition, these final regulations include an example illustrating the application of these final regulations to an in-place above-market lease that produces both income that qualifies as rents from real property under section 856(d)(1) and other income that does not so qualify.

C. Intangible Assets That Result From Mergers, Certain Business Combinations, and Stock or Asset Acquisitions

Section 1.856–10(f)(1) of the proposed regulations generally defined an intangible asset to include certain intangible assets established under generally accepted accounting principles (GAAP) as a result of an acquisition of real property or an interest in real property. Commenters noted that intangible assets may result from mergers, certain business combinations, and stock or asset acquisitions. The commenters urged that the final regulations acknowledge that REITs may acquire intangible assets in both asset and stock transactions.

The proposed regulations used the acquisition of real property or an interest in real property as an example of a type of transaction in which an intangible asset may be established under GAAP. Under § 1.856–2(d)(3), the term total assets means the gross assets of the REIT determined in accordance with GAAP. Thus, an intangible asset that, in accordance with GAAP, results from a merger, business combination, or stock or asset acquisition may qualify as real property. Because the proposed regulations did not preclude real property treatment of intangible assets resulting from mergers, certain business combinations, or stock or asset acquisitions, the Treasury Department and the IRS have concluded that no change is necessary to the final regulations to accommodate the commenter's concern.

D. Use Permits and Leases Requiring Property To Be Operated for a Specific Use

Section 856(c)(5)(C) defines interests in real property to include leaseholds of land or improvements thereon. Section 1.856–10(f)(2) of the proposed regulations stated that, if a license, permit, or other similar right solely for the use, enjoyment, or occupation of land or an IPS is in the nature of a leasehold or easement, that right generally is an interest in real property. However, a license or permit to engage in or operate a business generally is not real property or an interest in real property because the license or permit produces or contributes to the production of income other than consideration for the use or occupancy of space.

Section 1.856–10(g), *Example 12,* of the proposed regulations concluded that a special use permit from a government that, under governmental regulations, was not a lease of the land but was a permit to use the land for a cell tower was an interest in real property. Section 1.856–10(g), *Example 13,* of the proposed regulations illustrated that a license from a government to operate a casino in a specific building is a license to engage in the business of operating a casino and is not real property.

A commenter noted that many leases require property to be operated for a specific use. A property owner has an interest in requiring its property to be operated for its intended purpose. The commenter suggested that a specific-purpose lease should not be excluded from the definition of real property as an operating license.

The Treasury Department and the IRS generally agree that a requirement in a lease agreement that property be operated for a specific use does not cause the lease to fail to be treated as an interest in real property. A specific use requirement in a lease is distinguishable from a license or permit to operate a business. Such a requirement is generally a term or condition of a lease requiring that real property be used in the manner permitted by the property owner or landlord and does not constitute a separate grant by a governmental entity of the right to operate a business. *Example 12* concludes that a special use permit to use land for a specific purpose, a cell tower, is an interest in real property. Consistent with *Example 13,* if the special use permit in *Example 12* included a governmental authorization required to conduct a business that would produce income other than consideration for the use or occupancy of space, that portion of the special use permit would not be real property for purposes of these rules. Therefore, the Treasury Department and the IRS do not believe that any change in the proposed regulations is needed to address the commenter's concern.

E. Treatment of Intangible Assets in Another Context

A commenter noted that goodwill is not considered real property for appraisal purposes. The commenter recommended that goodwill be characterized as something other than real property, but nevertheless be provided the same tax treatment as real property. The Treasury Department and the IRS do not agree with this recommendation. Section 856 governs the determination of whether an asset is real property for REIT qualification purposes. Under § 1.856–2(d)(3), the gross assets of the REIT are determined in accordance with GAAP. Therefore an asset determined in accordance with GAAP, such as GAAP goodwill, must for purposes of sections 856 through 859 be accounted for either as real property or as property that is not real property. Although section 856(c)(5)(J)(ii) permits the Secretary to determine that an item of income that is not otherwise qualifying REIT income is considered as gross income that is qualifying REIT income, section 856 does not include a similar provision to permit an asset that is not otherwise real property to be treated as real property.

VIII. Procedural and Administrative Matters

A. Previously Issued Letter Rulings

A commenter requested that the final regulations provide that taxpayers may continue to rely on previously issued letter rulings. Section 11.04 of Rev. Proc. 2016–1[12] states that a letter ruling may be revoked or modified by the issuance of temporary or final regulations that are inconsistent with that letter ruling. Accordingly, to the extent a previously issued letter ruling is inconsistent with these final regulations, the letter ruling is revoked prospectively from the applicability date of these final regulations.

B. Revised Applicability Date and Election To Apply These Final Regulations to Earlier Quarters

The proposed regulations' applicability date was for calendar quarters beginning after the date that the proposed regulations are published as final regulations in the **Federal Register**. Commenters requested that the final regulations apply to taxable years beginning after the date that final regulations are published in the **Federal Register** and that taxpayers be permitted to apply the final regulations to earlier taxable years and quarters.

The Treasury Department and the IRS understand that an applicability date based on a calendar quarter may have unintended consequences in applying the gross income tests in section 856(c)(2) and (3) because those tests apply on an annual basis. For example, for rents to qualify as rents from interests in real property, the asset from which the rents are derived must qualify as real property. An asset that qualifies as real property before the applicability date, but not on or after the applicability date, would generate rents from real property only during quarters before the applicability date. These final regulations adopt this suggestion and apply to taxable years that begin after the date that the final regulations are published as final regulations in the **Federal Register**. In addition, because the Treasury Department and the IRS intend these final regulations generally to be a clarification of current law, taxpayers are permitted to rely on the final regulations for periods beginning on or before the applicability date. The applicability date for these final regulations is discussed further in this preamble in the "Applicability Date" section.

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[12] Rev. Proc. 2016–1, 2016–1 I.R.B. at 59.

IX. Interaction of the Definition of Real Property for Purposes of Sections 856 Through 859 With Other Code Provisions

A. Interaction of the Final Regulations With Other Provisions That Cross-Reference the Definition of Real Property for REIT Purposes

A commenter noted that § 1.860G–2(a)(4) references the definition of real property found in § 1.856–3(d) of the 1962 Regulations for purposes of determining whether an obligation is "principally secured by an interest in real property" for regulated mortgage investment conduit qualification purposes. The proposed regulations were proposed to revise § 1.856–3(d) to read as follows: "See § 1.856–10 for the definition of real property." To the extent other Treasury regulations reference the definition of real property in § 1.856–3(d), § 1.856–3(d), as proposed in the NPRM and as amended by these final regulations, directs taxpayers to apply the definition found in § 1.856–10.

B. Reconciling Definitions of Real Property

The preamble to the proposed regulations discussed various Code provisions in which the term real property appears. Noting the diverse contexts and varying legislative purposes of the Code provisions in which the term real property appears, the Treasury Department and the IRS requested comments on the extent to which the various meanings of real property that appear in the Treasury regulations should be reconciled.

Several commenters were concerned that the term real property has different meanings as the term is applied for purposes of different Code provisions, which could lead to confusion and inconsistent treatment of taxpayers. A commenter noted that there is no Federal definition of real property and suggested that another Code provision's restrictions on the use of real property should not preclude a REIT from investing in or financing such real property so long as the property is otherwise inherently permanent. Another commenter noted that under section 197, certain intangible assets are amortized as separate assets not associated with another asset. A third commenter requested clarification that the final regulations apply only to the definition of real property for purposes of sections 856 through 859, so that there is no conflict between the REIT provisions and other provisions of the Code that govern the investment tax credit and depreciation.

As discussed in the preamble to the proposed regulations, in drafting the proposed regulations, the Treasury Department and the IRS sought to balance (1) the general principle that common terms used in different provisions should have common meanings with (2) the particular policies underlying the definition used in the REIT provisions. These final regulations retain the language in § 1.856–10(a) of the proposed regulations stating that § 1.856–10 provides definitions for purposes of part II, subchapter M, chapter 1 of the Code. This language addresses the commenters' concerns by limiting the application of the definition of real property under these final regulations to sections 856 through 859.

X. Environmental Concerns

Some commenters suggested that the proposed regulations would encourage building in, on, or above water, which these commenters suggested is dangerous to water ecosystems and fish habitats. The commenters also suggested that the aftermath of hurricanes such as Katrina and Sandy should have demonstrated to the Government that development near or on water is dangerous to humans and extremely costly.

Neither section 856 nor the regulations thereunder override any environmental rules or regulations that may restrict development in these areas. In defining land, the Treasury Department and the IRS have concluded that it is important to include water space superjacent to land because rights to this water space are analytically indistinguishable from rights to air space superjacent to land, which, as discussed in this preamble, are treated as real property. *See* Rev. Rul. 71–286.

XI. Renewable Energy

A. Consequence of Net Metering on an Asset's Qualification as Real Property

Under § 1.856–10(d)(3)(i) of the proposed regulations, to qualify as real property, a structural component must serve an IPS and, even if capable of producing income other than consideration for the use or occupancy of space, must not produce or contribute to the production of such income. The preamble to the proposed regulations indicated that the Treasury Department and the IRS are considering guidance to address the treatment of any income earned when a system that provides electricity to an IPS held by a REIT also transfers excess electricity to a utility company. Commenters questioned whether a structural component would maintain its qualification as real property if the structural component served an IPS in its passive function but also produced a product, such as electricity, that was provided to third parties. One commenter suggested that the relevant test should be whether or not the property has net sales of electricity to the grid. Another commenter noted that the amount of electricity a building may net meter is regulated by the marketplace because utility companies often limit the percentage or amount of electricity that a building may net meter.

The Treasury Department and the IRS are considering whether additional guidance is necessary to address the circumstances under which a distinct asset that serves an IPS may produce electricity that is also sold to third parties and qualify as a structural component of the IPS for REIT purposes. Until additional guidance is published in the Internal Revenue Bulletin, in any taxable year in which (1) the quantity of excess electricity transferred to the utility company during the taxable year from such distinct assets does not exceed (2) the quantity of electricity purchased from the utility company during the taxable year to serve the IPS, the IRS (x) will not treat the transfer of such excess electricity as affecting the qualification of such distinct assets as structural components of the IPS for REIT purposes, (y) will exercise its authority under section 856(c)(5)(J)(i) to treat any income resulting from the transfer of such excess electricity as not constituting gross income for purposes of section 856(c)(2) and (3), and (z) will not treat any net income resulting from the transfer of such excess electricity as constituting net income derived from a prohibited transaction under section 857(b)(6).

B. Qualification of Renewable Energy Credits as Real Property for Purposes of Sections 856 Though 859

Commenters requested that the final regulations address the qualification of renewable energy credits (RECs) as real property. Renewable energy credits are credits issued to a provider of renewable energy and may be freely bought and sold. The owner of a system that produces renewable energy may sell RECs without selling the system or the electricity produced by the system.

Because RECs are intangible assets, the Treasury Department and the IRS have determined that RECs should be analyzed as such under § 1.856–10(f) of these final regulations. Thus, RECs do not qualify as intangible real property assets under these final regulations because RECs may be sold separately from any real property to which they relate.

C. Treatment of Renewable Energy Assets as Real Property as a Matter of Public Policy

Commenters urged the Treasury Department and the IRS to allow REITs to invest in solar energy sites as a means of furthering clean energy objectives. These commenters requested that investors in solar energy have the same access to REIT financing as investors in conventional energy sources such as natural gas, oil, and other fossil and electric energy property. Other commenters noted that private investment would be encouraged by treating certain electricity generating assets as real property.

Congress has not provided for solar energy assets to be treated differently from other assets for purposes of determining whether the assets qualify as real property under the REIT provisions. For this reason, the final regulations do not adopt this suggestion.

D. Treatment of Sunlight and Wind Rights as Interests in Land

Commenters suggested that sunlight used to power a solar energy site should be considered either real property or an interest in real property. One commenter analogized sunlight and wind to rights to air space, suggested that a REIT should be allowed to sell the rights to the sunlight or wind enjoyed on its property to third parties, and further suggested that a REIT should be able to treat income from the sale of such rights as qualifying income. This commenter posited that the process used to convert sunlight into electricity is analogous to the process inherent in fruit-bearing plants, which are discussed in § 1.856–10(g), *Example 1*, of the proposed regulations, and that the sunlight, like the plants in *Example 1*, should be treated as real property. Another commenter characterized sunlight as a resource analogous to oil, gas, and mineral resources inherent in land.

The Treasury Department and the IRS agree that a REIT may lease the air space superjacent to its land, which is an interest in its land, and may allow its tenants access to sunlight and wind. The Treasury Department and the IRS, however, are not aware of an approach that could be used to enable a REIT to rent or grant an interest in sunlight or wind separate from its interest in the land or the air space superjacent to the land. Therefore, these final regulations do not adopt these suggestions.

E. Qualification of a Concentrating Solar Power System and its Associated Assets as Real Property for Purposes of Sections 856 Trough 859

A commenter suggested that a concentrating solar power system uses assets that differ from PV panels to harvest solar energy. This commenter suggested that a concentrating solar power system, including, for example, a parabolic trough system, should be considered real property under these final regulations.

The Treasury Department and the IRS have concluded that this type of system is comprised of many distinct assets that may serve different functions. As illustrated in § 1.856–10(g), *Examples 8* and *9*, these distinct assets may be analyzed using the standards provided in the final regulations for OIPSs and structural components. Accordingly, concentrating solar power systems and their associated assets are not added to the lists of qualifying assets in these final regulations.

XII. Examples

Section 1.856–10(g) of the proposed regulations provided thirteen examples illustrating the application of the proposed regulations in a variety of factual scenarios.

A. References to Net Leases

Each of § 1.856–10(g), *Examples 1, 5, 6, 7, 8,* and *10*, of the proposed regulations stated that the REIT enters into a long term, triple-net lease of property. A commenter noted that the term "net lease" is not defined for purposes of section 856 and, therefore, may encompass different economic arrangements, the variations in which are not relevant to whether property is real property. The commenter further contended that many REITs do not net lease their assets. The commenter suggested that if it is necessary to describe the underlying facts, the term "lease" is sufficient and avoids the implication that a REIT must net lease its asset.

Each of *Examples 1, 5, 6, 7, 8,* and *10* of the proposed regulations stated that the assets are net leased to avoid any potential implication that the REIT is operating the property. *Examples 1, 5, 6, 7, 8,* and *10* are revised in these final regulations to provide that the REIT neither operates the property nor provides services to the lessee.

B. Example 4

Section 1.856–10(g), *Example 4*, of the proposed regulations analyzed whether a bus shelter is an IPS. One commenter suggested that *Example 4* be deleted because it was uncertain if a REIT would make a section 1033(g)[13] election with respect to the bus shelter. Additionally, the commenter was not aware of any REIT that leases or intends to lease bus shelters to a transit authority and believed that such shelters are rarely relocated. For these reasons, the commenter recommended that the example be stricken. No commenters, however, disagreed with the conclusion in the example.

The Treasury Department and the IRS believe that *Example 4* is helpful because it describes a structure that is not permanently affixed and thus does not qualify as an IPS under the standards provided in the regulations. Therefore, these final regulations do not adopt this suggestion.

C. Example 6

Section 1.856–10(g), *Example 6*, of the proposed regulations illustrated the definition of structural component in the context of a data center. One commenter suggested changes to *Example 6* including clarification that the electrical system and telecommunication infrastructure systems are (1) embedded in significant part within the walls and floors of the building, (2) would be difficult to remove, and (3) are intended to remain in place indefinitely. Although suggestions (1) and (2) would clarify the example and would not affect the analysis or conclusion of the example, suggestion (3) is not relevant because the structural component factors in § 1.856–10(d)(3)(ii)(B) of the proposed regulations do not include the intent of the owner of the asset. Accordingly, these final regulations revise *Example 6* to accurately reflect the integration of these assets into the data center building.[14]

Another commenter suggested that cross-connects used in a data center should not be considered real property because the cross-connects produce income that is not for the use or occupancy of space and this income is significant in comparison to the income produced by other assets in a data center. *Example 6* did not, and was not intended to, address every distinct asset that may be part of a data center. Distinct assets that are not addressed in the example may be analyzed by applying the standards set forth in the proposed regulations. Accordingly, no change was made to the final regulation in response to this comment.

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[13] Section 1033(g)(3) provides that a taxpayer may elect to treat property that constitutes an outdoor advertising display as real property for purposes of chapter 1 of the Code.

[14] For consistency and clarity, similar revisions have been made to other examples illustrating the definition of structural component.

E. Example 8

Section 1.856–10(g), *Example 8,* of the proposed regulations analyzed a solar energy site that includes land, photovoltaic modules (PV modules), mounts and an exit wire. The solar energy site was triple-net leased to an operator who uses the assets to produce and transmit energy to an electrical power grid for sale to third parties. The example concluded that the land, mounts, and exit wire qualify as real property and that the PV modules do not qualify as IPSs because they convert solar energy into electricity, which is an active function.

One commenter requested that the Treasury Department and the IRS update *Example 8* to include an analysis of inverters, which the commenter contended serve an active function compared to PV modules, which the commenter contended are relatively passive. Another commenter elaborated on the function of the PV modules, above ground wiring, and inverters. The commenter proposed adding language to *Example 8* to state that these assets have no moving parts and are therefore passive.

The Treasury Department and the IRS have concluded that PV modules and inverters that are used in the generation of energy for sale to third parties do not qualify as IPSs under the proposed regulations. The Treasury Department and the IRS do not believe the inclusion of above ground wiring in *Example 8,* which already analyzes an exit wire, is necessary to illustrate the application of the rules in § 1.856–10 to above ground wiring. For these reasons, the final regulations do not adopt these suggestions.

F. Example 9

Section 1.856–10(g), *Example 9,* of the proposed regulations described a solar energy site similar to the solar energy site in *Example 8,* except that the solar energy site in *Example 9* is mounted on land adjacent to an office building owned by the REIT. Other than occasional transfers of electricity to the grid, the solar energy site in *Example 9* serves only the REIT's office building to which it is constituent. The solar energy site in *Example 9* of the proposed regulations qualifies as a structural component.

A commenter recommended revisions to the statements in *Example 9* that the solar energy site was (1) designed specifically for the particular office building of which it is a part and (2) expensive and time consuming to install and remove. The commenter stated that most materials used for solar rooftop and other smaller-scale installations are mass-produced and standardized and can be removed and reinstalled without major complications or damage. These final regulations revise *Example 9* to state that the size and other specifications of the solar energy system were established to serve the needs of the office building and that no facts indicate that the solar energy system will not remain in place indefinitely.

Another commenter requested clarification of the term "occasionally transfers." This commenter recommended changing "occasionally transfers" to "regularly transfers" in describing the transfer of energy from the solar energy site to a utility company. As discussed in section XI.A. of this preamble, the Treasury Department and the IRS are considering whether additional guidance is necessary to address this commenter's concern. Until the issuance of such additional guidance, the Treasury Department and the IRS (1) will not treat the transfer of the excess electricity as affecting the qualification of the distinct assets as structural components of the IPS for REIT purposes, (2) will exercise its authority under section 856(c)(5)(J)(i) to treat any income resulting from the transfer of the excess electricity as not constituting gross income for purposes of section 856(c)(2) and (3), and (3) will not treat any net income resulting from the transfer of the excess electricity as constituting net income derived from a prohibited transaction under section 857(b)(6).

A commenter noted that even when a building uses all of the solar electricity produced by a solar energy site, such as the one in *Example 9,* the tenant of the building may earn income through the sale of RECs awarded under a local renewable portfolio standard. The Treasury Department and the IRS believe that income earned by a tenant from RECs in this situation would not affect the qualification of the solar energy site as a structural component. The tax consequences of income earned by a REIT from RECs are beyond the scope of this guidance.

Another commenter requested that *Example 9* be modified to address wind facilities rather than solar facilities. The Treasury Department and the IRS believe that the components of wind facilities may similarly be analyzed using the standards provided in § 1.856–10(d)(3) of the proposed regulations. For these reasons, the final regulations do not adopt these recommendations.

G. Example 10

Section 1.856–10(g), *Example 10,* of the proposed regulations addressed application of the proposed regulations to a pipeline transmission system. Distinct assets of the pipeline transmission system include underground pipelines, storage tanks, valves, vents, meters, and compressors. The example stated that the pipeline transmission system serves a passive function, containing oil, and an active function, transporting oil. The example further stated that, even though the pipeline transmission system serves an active function, a distinct asset within the system may nevertheless be an IPS if that asset does not perform an active function.

One commenter noted that whether the entire system performs an active function is not relevant because the system is composed of distinct assets, each of which must be separately analyzed. The Treasury Department and the IRS believe that *Example 10* is helpful because it demonstrates that a distinct asset within a system may still qualify as an IPS, or a structural component thereof, even though the system serves an active function.

As discussed in section III.A.2. of this preamble, these final regulations include providing a conduit or route as a permitted passive function and retain transport, which has been clarified to mean cause to move, as a prohibited active function. The Treasury Department and the IRS have revised *Example 10* to illustrate that the pipelines in *Example 10* serve the passive function of providing a conduit.

Another commenter suggested revising *Example 10* so that the pipeline transmission system transports natural gas rather than oil and suggested changing the vents and valves to isolation valves and vents, pressure control valves, relief valves, and pressure regulating stations. The commenter also suggested that *Example 10* be revised to apply the factors set forth in the regulations to determine whether these assets are structural components. These final regulations incorporate this commenter's suggestions.

In addition, commenters argued that the compressors within a pipeline transmission system are analogous to elevators and escalators within a building, with the function of moving things or people within an IPS. One commenter noted that compressors may be viewed as performing a propelling function. Another commenter suggested that elevators and escalators serve a building by enabling access to taller buildings, higher levels of occupancy, and more efficient usage. Another commenter suggested that compressors enable the efficient use of space within a pipeline.

To qualify as a structural component, a distinct asset must serve an IPS in its passive function. The compressors that transport natural gas through the pipeline transmission system in *Example 10* do not serve the underground pipelines in their passive function of providing a conduit but rather cause the natural gas to move through the conduit, which is an active function. For this reason, these final regulations do not adopt these suggestions.

H. Example 11

Section 1.856–10(g), *Example 11*, of the proposed regulations addressed whether goodwill established under GAAP as a result of the acquisition of stock of a corporation that owned a hotel qualifies as real property for purposes of sections 856 through 859. This example stated that the amount of the acquisition cost allocated to the hotel was limited to the hotel's depreciated replacement cost. The example also stated that the difference between the amount paid for the acquired corporation's stock and the depreciated replacement cost of the hotel was treated as goodwill attributable to the acquired hotel. The Treasury Department and the IRS have been advised that depreciated replacement cost is no longer the standard under GAAP for valuing property such as the hotel. The Treasury Department and the IRS have therefore removed this example.

I. Example 13

Section 1.856–10(g), *Example 13*, of the proposed regulations addressed whether a license to operate a casino is real property. *Example 13* concluded that because the license permits the holder to engage in the business of operating a casino the license is not real property even though the license applies only to the REIT's building and cannot be transferred to another location.

One commenter stated that in some foreign jurisdictions, a casino license may be more in the nature of a zoning permit that may be transferred to a subsequent buyer. This commenter suggested that a license that runs with the land is more in the nature of a zoning permit. The commenter recommended either deleting *Example 13* or revising it to distinguish transferable zoning-based or similar real estate-based licenses.

Another commenter noted that the permitted use of a facility for gaming purposes may enhance its value as real estate, apart from the value of the gaming license itself. The commenter also remarked that zoning laws frequently restrict gaming activities or liquor sales to particular geographical areas or locations, which restrictions, in general, favorably affect the value of real estate in these areas or locations.

These final regulations do not adopt these recommendations. Under § 1.856–10(f) of the proposed regulations, whether a license runs with the land is not dispositive in determining whether the license is real property for purposes of sections 856 through 859. The valuation of real property, including any effect that zoning may have on the value of real property, are beyond the scope of these final regulations.

J. Additional Examples

The Treasury Department and the IRS received requests to add additional examples to the final regulations.

Section VII.B. of this preamble describes comments received requesting clarification that intangible assets related to in-place above-market leases in which the REIT is the lessor and below-market leases in which the REIT is the lessee be treated as qualifying real property. As discussed in section VII.B., these final regulations include § 1.856–10(g), *Example 11*, which illustrates the application of these final regulations to an in-place above-market lease that produces both rents from real property under section 856(d)(1) and other income that does not qualify as rents from real property under section 856(d)(1).

A commenter suggested adding an example applying these final regulations to an electric transmission and distribution system. The Treasury Department and the IRS believe that the distinct assets of an electric transmission and distribution system are similar in many respects to the distinct assets of the solar energy site addressed by § 1.856–10(g), *Example 8* of the proposed regulations, and may be analyzed using the standards provided in § 1.856–10(d)(2) and (3) of the proposed regulations. Accordingly, these final regulations adequately address the distinct assets that may be part of an electrical transmission and distribution system.

Another commenter suggested that the final regulations include an example illustrating the components of an in-ground swimming pool. (The proposed regulations listed the pool itself as an OIPS.) The Treasury Department and the IRS are not aware that there have been significant questions concerning whether the various components qualify as real property. Therefore, these final regulations do not include an example addressing whether these components qualify as real property for purposes of sections 856 through 859.

XIII. Additional Comments

A. Potential Tax Inequality Among Taxpayers

Three commenters viewed the proposed regulations as a substantial expansion of the definition of real property. The Treasury Department and the IRS believe that the proposed regulations and these final regulations generally clarify existing law. These commenters also called for equal application of the tax laws and appear to believe that REITs are a vehicle that some corporations use to avoid taxes. The REIT structure was established by Congress in 1960, and it is not within the scope of these final regulations to change the REIT structure as these commenters suggest.

B. Clarification That Buildings Can Be on or Inside of Other Buildings or IPSs

A commenter requested that the final regulations clarify that buildings can be on or inside of other buildings or IPSs. The Treasury Department and the IRS believe that this comment was adequately addressed by the proposed regulations, which provided that the affixation of an IPS (which may be a building) may be to land or to another IPS. In addition, § 1.856–10(g), *Example 3*, concludes that a large sculpture inside an office building qualifies as an IPS. A building inside another building is not analytically different from the sculpture inside the building in *Example 3*. Accordingly, the proposed regulations, as finalized by this Treasury decision, adequately address this commenter's concern.

C. Qualification of Appurtenances and Zoning and Similar Rights

A commenter suggested that appurtenances should be included in the definition of land. The commenter suggested that real estate law provides that an appurtenance encompasses easements and rights of way over another's land to access one's own land. In addition, this commenter suggested that zoning and similar rights should be included in the definition of real property.

Taxpayers should apply § 1.856–10(f)(2) of these final regulations, which addresses the treatment of rights for the use, enjoyment, or occupation of land, to determine whether an appurtenance qualifies as real property for purposes of sections 856 through 859. Zoning rights may increase the value of real property. Consistent with § 1.856–2(d)(3), if a zoning right is considered a separate asset under GAAP, then the zoning right should be analyzed as an intangible asset under section 1.856–10(f) of these final regulations.

D. Additional Comments

A commenter suggested that the final regulations address the definition of rents from real property, eliminate the standard requiring that total assets be based on GAAP, and regulate the type of services that a taxable REIT subsidiary may provide. These issues are beyond the scope of these final regulations.

Effective/Applicability Date

These final regulations apply to taxable years that begin after August 31, 2016. Under section 856(c)(4), whether a taxpayer loses status as a REIT in one quarter may depend on whether the taxpayer satisfied section 856(c)(4) at the close of one or more prior quarters. For purposes of applying the first sentence of the flush language in section 856(c)(4) to a quarter in a taxable year that begins after August 31, 2016, these final regulations apply in determining whether the taxpayer met the requirements of section 856(c)(4) at the close of prior quarters. Taxpayers may rely on these final regulations for quarters that end before the applicability date.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business. No comments were received.

Drafting Information

The principal author of these regulations is Julanne Allen, Office of Associate Chief Council (Financial Institutions and Products). However, other personnel from the Treasury Department and the IRS participated in their development.

Statement of Availability of IRS Documents

The IRS revenue rulings and revenue procedure cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS Web site at *www.irs.gov.*

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.856–3(d) is revised to read as follows:

§ 1.856–3 Definitions.

* * * * *

(d) *Real property.* See § 1.856–10 for the definition of *real property.* A regulation that adopts the definition of real property in this paragraph is to be interpreted as if it had referred to § 1.856–10.

* * * * *

■ **Par. 3.** Section 1.856–10 is added to read as follows:

§ 1.856–10 Definition of real property.

(a) *In general.* This section provides definitions for purposes of part II, subchapter M, chapter 1 of the Internal Revenue Code. Paragraph (b) of this section defines real property, which includes land as defined under paragraph (c) of this section and improvements to land as defined under paragraph (d) of this section. Improvements to land include inherently permanent structures as defined under paragraph (d)(2) of this section and structural components of inherently permanent structures as defined under paragraph (d)(3) of this section. Paragraph (e) of this section provides rules for determining whether an item is a distinct asset for purposes of applying the definitions in paragraphs (b), (c), and (d) of this section. Paragraph (f) of this section identifies intangible assets that are real property or interests in real property. Paragraph (g) of this section provides examples illustrating the rules of paragraphs (b) through (f) of this section. Paragraph (h) of this section provides the effective/applicability date for this section.

(b) *Real property.* The term *real property* means land and improvements to land. Local law definitions are not controlling for purposes of determining the meaning of the term real property.

(c) *Land.* Land includes water and air space superjacent to land and natural products and deposits that are unsevered from the land. Natural products and deposits, such as crops, water, ores, and minerals, cease to be real property when they are severed, extracted, or removed from the land. The storage of severed or extracted natural products or deposits, such as crops, water, ores, and minerals, in or upon real property does not cause the stored property to be recharacterized as real property.

(d) *Improvements to land*—(1) *In general.* The term *improvements to land* means inherently permanent structures and their structural components.

(2) *Inherently permanent structure*—(i) *In general.* The term *inherently permanent structure* means any permanently affixed building or other permanently affixed structure. Affixation may be to land or to another inherently permanent structure and may be by weight alone. If the affixation is reasonably expected to last indefinitely based on all the facts and circumstances, the affixation is considered permanent. A distinct asset that serves an active function, such as an item of machinery or equipment, is not a building or other inherently permanent structure.

(ii) *Building*—(A) *In general.* A building encloses a space within its walls and is covered by a roof.

(B) *Types of buildings.* Buildings include the following distinct assets if permanently affixed: Houses; apartments; hotels; motels; enclosed stadiums and arenas; enclosed shopping malls; factory and office buildings; warehouses; barns; enclosed garages; enclosed transportation stations and terminals; and stores.

(iii) *Other inherently permanent structures*—(A) *In general.* Other inherently permanent structures serve a passive function, such as to contain, support, shelter, cover, protect, or provide a conduit or a route, and do not serve an active function, such as to manufacture, create, produce, convert, or transport.

(B) *Types of other inherently permanent structures.* Other inherently permanent structures include the following distinct assets if permanently affixed: Microwave transmission, cell, broadcast, and electrical transmission towers; telephone poles; parking facilities; bridges; tunnels; roadbeds; railroad tracks; transmission lines; pipelines; fences; in-ground swimming pools; offshore drilling platforms; storage structures such as silos and oil and gas storage tanks; and stationary wharves and docks. Other inherently permanent structures also include outdoor advertising displays for which an election has been properly made under section 1033(g)(3).

(iv) *Facts and circumstances determination.* If a distinct asset (within the meaning of paragraph (e) of this section) does not serve an active function as described in paragraph (d)(2)(iii)(A) of this section and is not otherwise listed in paragraph (d)(2)(ii)(B) or (d)(2)(iii)(B) of this section or in guidance published in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii) of this chapter), the determination of whether that asset is an inherently permanent structure is based on all the facts and circumstances. In particular, the following factors must be taken into account:

(A) The manner in which the distinct asset is affixed to real property;

(B) Whether the distinct asset is designed to be removed or to remain in place indefinitely;

(C) The damage that removal of the distinct asset would cause to the item itself or to the real property to which it is affixed;

(D) Any circumstances that suggest the expected period of affixation is not indefinite (for example, a lease that requires or permits removal of the distinct asset upon the expiration of the lease); and

(E) The time and expense required to move the distinct asset.

(3) *Structural components*—(i) *In general.* The term *structural component* means any distinct asset (within the meaning of paragraph (e) of this section) that is a constituent part of and integrated into an inherently permanent structure, serves the inherently permanent structure in its passive function, and, even if capable of producing income other than consideration for the use or occupancy of space, does not produce or contribute to the production of such income. If interconnected assets work together to serve an inherently permanent structure with a utility-like function (for example, systems that provide a building with electricity, heat, or water), the assets are analyzed together as one distinct asset that may be a structural component. A structural component may qualify as real property only if the real estate investment trust (REIT) holds its interest in the structural component together with a real property interest in the space in the inherently permanent structure served by the structural component. A mortgage secured by a structural component is a real estate asset only if the mortgage is also secured by a real property interest in the inherently permanent structure served by the structural component. If a distinct asset is customized in connection with the rental of space in or on an inherently permanent structure to which the asset relates, the customization does not affect whether the distinct asset is a structural component.

(ii) *Types of structural components.* Structural components include the following distinct assets and systems if integrated into the inherently permanent structure and held together with a real property interest in the space in the inherently permanent structure served by that distinct asset or system: Wiring; plumbing systems; central heating and air-conditioning systems; elevators or escalators; walls; floors; ceilings; permanent coverings of walls, floors, and ceilings; windows; doors; insulation; chimneys; fire suppression systems, such as sprinkler systems and fire alarms; fire escapes; central refrigeration systems; security systems; and humidity control systems.

(iii) *Facts and circumstances determination.* If an interest in a distinct asset (within the meaning of paragraph (e) of this section) is held together with a real property interest in the space in the inherently permanent structure served by that distinct asset and that asset is not otherwise listed in paragraph (d)(3)(ii) of this section or in guidance published in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii) of this chapter), the determination of whether that asset is a structural component is based on all the facts and circumstances. In particular, the following factors must be taken into account:

(A) The manner, time, and expense of installing and removing the distinct asset;

(B) Whether the distinct asset is designed to be moved;

(C) The damage that removal of the distinct asset would cause to the item itself or to the inherently permanent structure to which it is affixed;

(D) Whether the distinct asset serves a utility-like function with respect to the inherently permanent structure;

(E) Whether the distinct asset serves the inherently permanent structure in its passive function;

(F) Whether the distinct asset produces income from consideration for the use or occupancy of space in or upon the inherently permanent structure;

(G) Whether the distinct asset is installed during construction of the inherently permanent structure; and

(H) Whether the distinct asset will remain if the tenant vacates the premises.

(e) *Distinct asset*—(1) *In general.* A distinct asset is analyzed separately from any other assets to which the asset relates to determine if the asset is real property, whether as land, an inherently permanent structure, or a structural component of an inherently permanent structure.

(2) *Facts and circumstances.* The determination of whether a particular separately identifiable item of property is a distinct asset is based on all the facts and circumstances. In particular, the following factors must be taken into account:

(i) Whether the item is customarily sold or acquired as a single unit rather than as a component part of a larger asset;

(ii) Whether the item can be separated from a larger asset, and if so, the cost of separating the item from the larger asset;

(iii) Whether the item is commonly viewed as serving a useful function independent of a larger asset of which it is a part; and

(iv) Whether separating the item from a larger asset of which it is a part impairs the functionality of the larger asset.

(f) *Intangible assets*—(1) *In general.* To the extent that an intangible asset, including an intangible asset established under generally accepted accounting principles (GAAP) as a result of an acquisition of real property or an interest in real property, derives its value from real property or an interest in real property, is inseparable from that real property or interest in real property, and does not produce or contribute to the production of income other than consideration for the use or occupancy of space, the intangible asset is real property or an interest in real property.

(2) *Licenses and permits.* A license, permit, or other similar right that is solely for the use, enjoyment, or occupation of land or an inherently permanent structure and that is in the nature of a leasehold or easement generally is an interest in real property. A license or permit to engage in or operate a business is not real property or an interest in real property if the

license or permit produces or contributes to the production of income other than consideration for the use or occupancy of space.

(g) *Examples.* The following examples demonstrate the rules of this section. *Examples 1* and *2* illustrate the definition of land as provided in paragraph (c) of this section. *Examples 3* through *10* illustrate the definition of improvements to land as provided in paragraph (d) of this section. Finally, *Examples 11* through *13* illustrate whether certain intangible assets are real property or interests in real property as provided in paragraph (f) of this section.

Example 1. Natural products of land. A is a REIT. REIT A owns land with perennial fruit-bearing plants. REIT A leases the fruit-bearing plants to a tenant and grants the tenant an easement to enter the land to cultivate the plants and to harvest the fruit. The lease and easement are long-term and REIT A provides no services to the tenant. The unsevered plants are natural products of the land and are land within the meaning of paragraph (c) of this section. The tenant annually harvests fruit from the plants. Upon severance from the land, the harvested fruit ceases to qualify as land. Storage of the harvested fruit upon or within real property does not cause the harvested fruit to be real property.

Example 2. Water space superjacent to land. REIT B leases a marina from a governmental entity. The marina is comprised of U-shaped boat slips and end ties. The U-shaped boat slips are spaces on the water that are surrounded by a dock on three sides. The end ties are spaces on the water at the end of a slip or on a long, straight dock. REIT B rents the boat slips and end ties to boat owners. The boat slips and end ties are water space superjacent to land that is land within the meaning of paragraph (c) of this section and, therefore, are real property.

Example 3. Indoor sculpture. (i) REIT C owns an office building and a large sculpture in the atrium of the building. The sculpture measures 30 feet tall by 18 feet wide and weighs five tons. The building was specifically designed to support the sculpture, which is permanently affixed to the building by supports embedded in the building's foundation. The sculpture was constructed within the building. Removal would be costly and time consuming and would destroy the sculpture. The sculpture is reasonably expected to remain in the building indefinitely. The sculpture does not manufacture, create, produce, convert, transport, or serve any similar active function.

(ii) The sculpture is not an asset listed in paragraph (d)(2)(iii)(B) of this section, and, therefore, the sculpture is an asset that must be analyzed to determine whether it is an inherently permanent structure using the factors provided in paragraph (d)(2)(iv) of this section. The sculpture—

(A) Is permanently affixed to the building by supports embedded in the building's foundation;

(B) Is not designed to be removed and is designed to remain in place indefinitely;

(C) Would be damaged if removed and would damage the building to which it is affixed;

(D) Will remain affixed to the building after any tenant vacates the premises and will remain affixed to the building indefinitely; and

(E) Would require significant time and expense to move.

(iii) The factors described in this paragraph (g) *Example 3* (ii)(A) through (E) all support the conclusion that the sculpture is an inherently permanent structure within the meaning of paragraph (d)(2) of this section and, therefore, is real property.

Example 4. Bus shelters. (i) REIT D owns 400 bus shelters, each of which consists of four posts, a roof, and panels enclosing two or three sides. REIT D enters into a long-term lease with a local transit authority for use of the bus shelters. Each bus shelter is prefabricated from steel and is bolted to the sidewalk. Bus shelters are disassembled and moved when bus routes change. Moving a bus shelter takes less than a day and does not significantly damage either the bus shelter or the real property to which it was affixed.

(ii) The bus shelters are not permanently affixed enclosed transportation stations or terminals and do not otherwise meet the definition of a building in paragraph (d)(2)(ii) of this section nor are they listed as types of other inherently permanent structures in paragraph (d)(2)(iii)(B) of this section. Therefore, the bus shelters must be analyzed to determine whether they are inherently permanent structures using the factors provided in paragraph (d)(2)(iv) of this section. The bus shelters—

(A) Are not permanently affixed to the land or an inherently permanent structure;

(B) Are designed to be removed and are not designed to remain in place indefinitely;

(C) Would not be damaged if removed and would not damage the sidewalks to which they are affixed;

(D) Will not remain affixed after the local transit authority vacates the site and will not remain affixed indefinitely; and

(E) Would not require significant time and expense to move.

(iii) The factors described in this paragraph (g) *Example 4* (ii)(A) through (E) all support the conclusion that the bus shelters are not inherently permanent structures within the meaning of paragraph (d)(2) of this section. Although the bus shelters serve a passive function of sheltering, the bus shelters are not permanently affixed, which means the bus shelters are not inherently permanent structures within the meaning of paragraph (d)(2) of this section and, therefore, are not real property.

Example 5. Cold storage warehouse. (i) REIT E owns a refrigerated warehouse (Cold Storage Warehouse). REIT E enters into a long-term lease with a tenant. REIT E neither operates the Cold Storage Warehouse nor provides services to its tenant. The tenant uses the Cold Storage Warehouse to store perishable products. Certain components and utility systems that are integrated into the Cold Storage Warehouse have been customized to accommodate the tenant's need for refrigerated storage space. For example, the Cold Storage Warehouse has customized freezer walls and a central refrigeration system. Freezer walls within the Cold Storage Warehouse are specifically designed to maintain the desired temperature within the Cold Storage Warehouse. The freezer walls and central refrigeration system comprise a series of interconnected assets that work together to serve a utility-like function within the Cold Storage Warehouse, were installed during construction of the building, and will remain in place when the tenant vacates the premises. The freezer walls and central refrigeration system were designed to remain permanently in place.

(ii) Walls and central refrigeration systems are listed as structural components in paragraph (d)(3)(ii) of this section and, therefore, are real property. The customization of the freezer walls does not affect their qualification as structural components of REIT E's Cold Storage Warehouse within the meaning of paragraph (d)(3) of this section. Therefore, the freezer walls and central refrigeration system are structural components of REIT E's Cold Storage Warehouse.

Example 6. Data center. (i) REIT F owns a building that it leases to a tenant under a long-term lease. REIT F neither operates the building nor provides services to its tenant. To accommodate the particular requirements for housing computer servers, certain interior components and utility systems within the building have been customized to provide a higher level of functionality than a conventional office building. These customized systems are owned by REIT F and include an electrical distribution and redundancy system (Electrical System), a central heating and air-conditioning system, a telecommunication infrastructure system, an integrated security system, a fire suppression system, and a humidity control system (each, a System). In addition, the space for computer servers in REIT F's building has been constructed with raised flooring that is integrated into the building to accommodate the Systems. Each System is comprised of a series of interconnected assets that work together to serve a utility-like function within the building. The Systems are integrated into the office building, were installed during construction of the building, and will remain in place when the tenant vacates the premises. Each of the Systems was customized to enhance the capacity of the System in connection with the rental of space within the building.

(ii) The central heating and air-conditioning system, integrated security system, fire suppression system, and humidity control system are listed as structural components in paragraph (d)(3)(ii) of this section and, therefore, are real property. The customization of these Systems does not affect the qualification of these Systems as structural components of REIT F's building within the meaning of paragraph (d)(3) of this section. Therefore, these Systems are structural components of REIT F's building.

(iii) In addition to wiring and flooring, which are listed as structural components in paragraph (d)(3)(ii) of this section and, therefore, are real property, the Electrical System and telecommunication infrastructure system include equipment used to ensure that the tenant is provided with uninterruptable, stable power and telecommunication services. The Electrical System and telecommunication infrastructure system are not listed in paragraph (d)(3)(ii) of this section, and, therefore, they must be analyzed to determine whether they are structural components of the building using the factors provided in paragraph (d)(3)(iii) of this section. The Electrical System and telecommunication infrastructure system—

(A) Are embedded within the walls and floors of the building and would be costly to remove;

(B) Are not designed to be moved and are designed specifically for the particular building of which they are a part;

(C) Would not be significantly damaged upon removal and, although removing them would damage the walls and floors in which they are embedded, their removal would not significantly damage the building;

(D) Serve a utility-like function with respect to the building;

(E) Serve the building in its passive functions of containing, sheltering, and protecting computer servers;

(F) Produce income as consideration for the use or occupancy of space within the building;

(G) Were installed during construction of the building; and

(H) Will remain in place when the tenant vacates the premises.

(iv) The factors described in this paragraph (g) *Example 6* (iii)(A), (B), and (D) through (H) all support the conclusion that the Electrical System and telecommunication infrastructure system are structural components of REIT F's building within the meaning of paragraph (d)(3) of this section and, therefore, are real property. The factor described in this paragraph (g) *Example 6* (iii)(C) would support a conclusion that the Electrical System and telecommunication infrastructure system are not structural components. However this factor does not outweigh the factors supporting the conclusion that the Electric System and telecommunication infrastructure system are structural components.

Example 7. Partitions. (i) REIT G owns an office building that it leases to tenants under long-term leases. REIT G neither operates the office building nor provides services to its tenants. Partitions are owned by REIT G and are used to delineate space between tenants and within each tenant's space. The office building has two types of interior, non-load-bearing drywall partition systems: a conventional drywall partition system (Conventional Partition System) and a modular drywall partition system (Modular Partition System). Neither the Conventional Partition System nor the Modular Partition System was installed during construction of the office building. Conventional Partition Systems are comprised of fully integrated gypsum board partitions, studs, joint tape, and covering joint compound. Modular Partition Systems are comprised of assembled panels, studs, tracks, and exposed joints. Both the Conventional Partition System and the Modular Partition System reach from the floor to the ceiling.

(ii) Depending on the needs of a new tenant, the Conventional Partition System may remain in place when a tenant vacates the premises. The Conventional Partition System is integrated into the office building and is designed and constructed to remain in areas not subject to reconfiguration or expansion. The Conventional Partition System can be removed only by demolition, and, once removed, neither the Conventional Partition System nor its components can be reused. Removal of the Conventional Partition System causes substantial damage to the Conventional Partition System itself but does not cause substantial damage to the building.

(iii) Modular Partition Systems are typically removed when a tenant vacates the premises. Modular Partition Systems are not designed or constructed to remain permanently in place. Modular Partition Systems are designed and constructed to be movable. Each Modular Partition System can be readily removed, remains in substantially the same condition as before, and can be reused. Removal of a Modular Partition System does not cause any substantial damage to the Modular Partition System itself or to the building. The Modular Partition System may be moved to accommodate the reconfigurations of the interior space within the office building for various tenants that occupy the building.

(iv) The Conventional Partition System is comprised of walls that are integrated into an inherently permanent structure, and thus are listed as structural components in paragraph (d)(3)(ii) of this section. The Conventional Partition System, therefore, is real property.

(v) The Modular Partition System is not integrated into the building and, therefore, is not listed in paragraph (d)(3)(ii) of this section. Thus, the Modular Partition System must be analyzed to determine whether it is a structural component using the factors provided in paragraph (d)(3)(iii) of this section. The Modular Partition System—

(A) Is installed and removed quickly and with little expense;

(B) Is designed to be moved and is not designed specifically for the particular building of which it is a part;

(C) Is not damaged, and the building is not damaged, upon its removal;

(D) Does not serve a utility-like function with respect to the building;

(E) Serves the building in its passive functions of containing and protecting the tenants' assets;

(F) Produces income only as consideration for the use or occupancy of space within the building;

(G) Was not installed during construction of the building; and

(H) Will not remain in place when a tenant vacates the premises.

(vi) The factors described in this paragraph (g) *Example 7* (v)(A) through (D), (G) and (H) all support the conclusion that the Modular Partition System is not a structural component of REIT G's building within the meaning of paragraph (d)(3) of this section and, therefore, is not real property. The factors described in this paragraph (g) *Example 7* (v)(E) and (F) would support a conclusion that the Modular Partition System is a structural component. These factors, however, do not outweigh the factors supporting the conclusion that the Modular Partition System is not a structural component.

Example 8. Solar energy site. (i) REIT H owns a solar energy site, among the components of which are land, photovoltaic modules (PV Modules), mounts and an exit wire. REIT H enters into a long-term lease with a tenant for the solar energy site. REIT H neither operates the solar energy site nor provides services to its tenant. The mounts support the PV Modules. The racks are affixed to the land through foundations made from poured concrete. The mounts will remain in place when the tenant vacates the solar energy site. The PV Modules convert solar photons into electric energy (electricity). The exit wire is buried underground, is connected to equipment that is in turn connected to the PV Modules, and transmits the electricity produced by the PV Modules to an electrical power grid, through which the electricity is distributed for sale to third parties.

(ii) REIT H's PV Modules, mounts, and exit wire are each separately identifiable items. Separation from a mount does not affect the ability of a PV Module to convert photons to electricity. Separation from the equipment to which it is attached does not affect the ability of the exit wire to transmit electricity to the electrical power grid. The types of PV Modules and exit wire that REIT H owns are each customarily sold or acquired as single units. Removal of the PV Modules from the mounts that support them does not damage the function of the mounts as support structures and removal is not costly. The PV Modules serve the active function of converting photons to electricity. Disconnecting the exit wire from the equipment to which it is attached does not damage the function of that equipment, and the disconnection is not costly. The PV Modules, mounts, and exit wire are each distinct assets within the meaning of paragraph (e) of this section.

(iii) The land is real property as defined in paragraph (c) of this section.

(iv) The mounts are designed and constructed to remain in place indefinitely, and they have a passive function of supporting the PV Modules. The mounts are not listed in paragraph (d)(2)(iii)(B) of this section, and, therefore, the mounts are assets that must be analyzed to determine whether they are inherently permanent structures using the factors provided in paragraph (d)(2)(iv) of this section. The mounts—

(A) Are permanently affixed to the land through the concrete foundations or molded concrete anchors (which are part of the mounts);

(B) Are not designed to be removed and are designed to remain in place indefinitely;

(C) Would be damaged if removed;

(D) Will remain affixed to the land after the tenant vacates the premises and will remain affixed to the land indefinitely; and

(E) Would require significant time and expense to move.

(v) The factors described in this paragraph (g) *Example 8* (iv)(A) through (E) all support the conclusion that the mounts are inherently permanent structures within the meaning of paragraph (d)(2) of this section and, therefore, are real property.

(vi) The PV Modules convert solar photons into electricity that is transmitted through an electrical power grid for sale to third parties. The conversion is an active function. Thus, the PV Modules are items of machinery or equipment and therefore are not inherently permanent structures within the meaning of paragraph (d)(2) of this section and, so, are not real property. The PV Modules do not serve the mounts in their passive function of providing support; instead, the PV Modules produce electricity for sale to third parties, which is income other than consideration for the use or occupancy of space. Thus, the PV Modules are not structural components of REIT H's mounts within the meaning of paragraph (d)(3) of this section and, therefore, are not real property.

(vii) The exit wire is buried under the ground and transmits the electricity produced by the PV Modules to the electrical power grid. The exit wire was installed during construction of the solar energy site and is designed to remain permanently in place. The exit wire is permanently affixed and is a transmission line, which is listed as an inherently permanent structure in paragraph (d)(2)(iii)(B) of this section. Therefore, the exit wire is real property.

Example 9. Solar-powered building. (i) REIT I owns a solar energy site similar to that described in *Example 8,* except that REIT I's solar energy site assets (Solar Energy Site Assets) are mounted on land adjacent to an office building owned by REIT I. REIT I leases the office building and the solar energy site to a single tenant. REIT I does not operate the office building or the solar energy site and does not provide services to its tenant. Although the tenant occasionally transfers excess electricity produced by the Solar Energy Site Assets to a utility company, the Solar Energy Site Assets are designed and intended to produce electricity only to serve the office building. The size and specifications of the Solar Energy Site Assets were designed to be appropriate to serve only the electricity needs of the office building. Although the Solar Energy Site Assets were not installed during construction of the office building, no facts indicate either that the Solar Energy Site Assets will not remain in place indefinitely or that they may be removed if the tenant vacates the premises.

(ii) With the exception of the occasional transfers of excess electricity to a utility company, the Solar Energy Site Assets serve the office building to which they are adjacent, and, therefore, the Solar Energy Site Assets are analyzed to determine whether they are a structural component using the factors provided in paragraph (d)(3)(iii) of this section. The Solar Energy Site Assets—

(A) Are expensive and time consuming to install and remove;

(B) Were designed with the size and specifications needed to serve only the office building;

(C) Will be damaged, but will not cause damage to the office building, upon removal;

(D) Serve a utility-like function with respect to the office building;

(E) Serve the office building in its passive functions of containing, sheltering, and protecting the tenant and the tenant's assets;

(F) Produce income from consideration for the use or occupancy of space within the office building;

(G) Were not installed during construction of the office building; and

(H) Will remain in place when the tenant vacates the premises.

(iii) The factors described in this paragraph (g) *Example 9* (ii)(A) through (C) (in part), (ii)(D) through (F), and (ii)(H) all support the conclusion that the Solar Energy Site Assets are a structural component of REIT I's office building within the meaning of paragraph (d)(3) of this section and, therefore, are real property. The factors described in this paragraph (g) *Example 9* (ii)(C) (in part) and (ii)(G) would support a conclusion that the Solar Energy Site Assets are not a structural component, but these factors do not outweigh the factors supporting the conclusion that the Solar Energy Site Assets are a structural component.

(iv) The result in this *Example 9* would not change if, instead of the Solar Energy Site Assets, solar shingles were used as the roof of REIT I's office building. Solar shingles are roofing shingles like those commonly used for residential housing, except that they contain built-in PV modules. The solar shingle installation was specifically designed and constructed to serve only the needs of REIT I's office building, and the solar shingles were installed as a structural component to provide solar energy to REIT I's office building (although REIT I's tenant occasionally transfers excess electricity produced by the solar shingles to a utility company). The analysis of the application of the factors provided in paragraph (d)(3)(ii) of this section would be similar to the analysis of the application of the factors to the Solar Energy Site Assets in this paragraph (g) *Example 9* (ii) and (iii).

Example 10. Pipeline transmission system. (i) REIT J owns a natural gas pipeline transmission system that provides a conduit to transport natural gas from unrelated third-party producers and gathering facilities to unrelated third-party distributors and end users. REIT J enters into a long-term lease with a tenant for the pipeline transmission system. REIT J neither operates the pipeline transmission system nor provides services to its tenant. The pipeline transmission system is comprised of underground pipelines, isolation valves and vents, pressure control and relief valves, meters, and compressors. Although the pipeline transmission system as a whole serves an active function (transporting natural gas), one or more distinct assets within the system may nevertheless be inherently permanent structures that do not themselves perform active functions. Each of these distinct assets was installed during construction of the pipeline transmission system and will remain in place when the tenant vacates the pipeline transmission system. Each of these assets was designed to remain permanently in place.

(ii) The pipelines are permanently affixed and are listed as other inherently permanent structures in paragraph (d)(2)(iii)(B) of this section. Therefore, the pipelines are real property.

(iii) Isolation valves and vents are placed at regular intervals along the pipelines to isolate and evacuate sections of the pipelines in case there is need for a shut-down or maintenance of the pipelines. Pressure control and relief valves are installed at regular intervals along the pipelines to provide overpressure protection. The isolation valves and vents and pressure control and relief valves are not listed in paragraph (d)(3)(ii) and, therefore, must be analyzed to determine whether they are structural components using the factors provided in paragraph (d)(3)(iii) of this section. The isolation valves and vents and pressure control and relief valves—

(A) Are time consuming and expensive to install and remove from the pipelines;

(B) Are designed specifically for the particular pipelines for which they are a part;

(C) Will sustain damage and will damage the pipelines if removed;

(D) Do not serve a utility-like function with respect to the pipelines;

(E) Serve the pipelines in their passive function of providing a conduit for natural gas;

(F) Produce income only from consideration for the use or occupancy of space within the pipelines;

(G) Were installed during construction of the pipelines; and

(H) Will remain in place when the tenant vacates the premises.

(iv) The factors described in this paragraph (g) *Example 10* (iii)(A) through (C) and (iii)(E) through (H) support the conclusion that the isolation valves and vents and pressure control and relief valves are structural components of REIT J's tanks or pipelines within the meaning of paragraph (d)(3) of this section and, therefore, are real property. The factor described in this paragraph (g) *Example 10* (iii)(D) would support a conclusion that the isolation valves and vents and pressure control and relief valves are not structural components, but this factor does not outweigh the factors that support the conclusion that the isolation valves and vents and pressure control and relief valves are structural components.

(v) Meters are used to measure the natural gas passing into or out of the pipeline transmission system for purposes of determining the end users' consumption. Over long distances, pressure is lost due to friction in the pipeline transmission system. Compressors are required to add pressure to transport natural gas through the entirety of the pipeline transmission system. The meters and compressors do not serve the tanks or pipelines in their passive function of providing a conduit for the natural gas, and are used in connection with the production of income from the sale and transportation of natural gas, rather than as consideration for the use or occupancy of space within the pipelines. The meters and compressors are not structural components within the meaning of paragraph (d)(3) of this section and, therefore, are not real property.

Example 11. Above-market lease. REIT K acquires an office building from an unrelated third party subject to a long-term lease with a single tenant under which the tenant pays above-market rents. The above-market lease is an intangible asset under GAAP. Seventy percent of the value of the above-market lease asset is attributable to income from the long-term lease that qualifies as rents from real property, as defined in section 856(d)(1). The remaining thirty percent of the value of the above-market lease asset is attributable to income from the long-term lease that does not qualify as rents from real property. The portion of the value of the above-market lease asset that is attributable to rents from real property (here, seventy percent) derives its value from real property, is inseparable from that real property, does not produce or contribute to the production of income other than consideration for the use or occupancy of space, and, therefore, is an interest in real property under section 856(c)(5)(C) and a real estate asset under section 856(c)(5)(B). The remaining portion of the above-market lease asset does not derive its value from real property and, therefore, is not a real estate asset.

Example 12. Land use permit. REIT L receives a special use permit from the government to place a cell tower on Federal Government land that abuts a federal highway. Government regulations provide that the permit is not a lease of the land, but is a permit to use the land for a cell tower. Under the permit, the government reserves the right to cancel the permit and compensate REIT L if the site is needed for a higher public purpose. REIT L leases space on the tower to various cell service providers. Each cell service provider installs its equipment on a designated space on REIT L's cell tower. The permit does not produce, or contribute to the production of, any income other than REIT L's receipt of payments from the cell service providers in consideration for their being allowed to use space on the tower. The permit is in the nature of a leasehold that allows REIT L to place a cell tower in a specific location on government land. Therefore, the permit is an interest in real property.

Example 13. License to operate a business. REIT M owns a building and receives a license from State to operate a casino in the building. The license applies only to REIT M's building and cannot be transferred to another location. REIT M's building is an inherently permanent structure under paragraph (d)(2)(i) of this section and, therefore, is real property. However, REIT M's license to operate a casino is not a right for the use, enjoyment, or occupation of REIT M's building but is rather a license to engage in the business of operating a casino in the building. Therefore, the casino license is not real property.

(h) *Effective/applicability date.* The rules of this section apply for taxable years beginning after August 31, 2016. For purposes of applying the first sentence of the flush language of section 856(c)(4) to a quarter in a taxable year that begins after August 31, 2016, the rules of this section apply in determining whether the taxpayer met the requirements of section 856(c)(4) at the close of prior quarters. Taxpayers may rely on this section for quarters that end before the applicability date.

Approved: August 8, 2016.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–20987 Filed 8–30–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0665]

RIN 1625–AA00

Safety Zone; Great Egg Harbor Bay, Marmora, NJ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones on the waters of Great Egg Harbor Bay in Marmora, NJ. The first safety zone includes all waters within 250 feet of vessel and machinery conducting demolition operations on the remaining portions of the Route 9, Beesley Point Bridge bascule span. This safety zone is necessary to provide for the safety of life on navigable waters during the demolition and will re-route vessel traffic through an alternate channel to facilitate heavy marine equipment operating in the main navigational channel to remove the bascule span of the bridge and will be in place throughout the entire duration of the demolition work.

The second safety zone includes all waters within 500 yards of a blasting vessel and equipment being used to conduct bridge pile blasting operations, which is the final phase of the demolition of the Route 9, Beesley Point Bridge bascule span. This safety zone will only be enforced during times of explosive detonation. The safety zone will temporarily restrict vessel traffic from transiting or anchoring in a portion of the Great Egg Harbor Bay while pile blasting and removal operations are being conducted to facilitate the removal of bridge piles from the demolished Route 9, Beesley Point Bridge.

DATES: This rule is effective without actual notice from August 31, 2016 through October 20, 2016. For the purposes of enforcement, actual notice will be used from August 22, 2016, until August 31, 2016. The second safety zone will be enforced on or about October 1, 2016, only during times of explosive detonation.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to, type USCG–2016–0665 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Marine Science Technician First Class Tom Simkins, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, Coast Guard; telephone (215) 271–4889, email *Tom.J.Simkins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code
COTP	Captain of the Port

II. Background Information and Regulatory History

In June of 2013, demolition work began on the Route 9, Beesley Point Bridge between Somers Point and Marmora, NJ. Route 52 Construction, the company performing this demolition work, has completed all demolition of the bridge and piles except the portion of the bridge which has the bascule span opening for the navigational channel.

During this phase of demolition heavy marine equipment, to include a large crane and barge, will be used to remove the large bascule span arms and what is left of the bridge tender house and roadway. The barge and crane must be placed in the navigational channel to properly secure and remove what remains of the bridge.

All piles from the demolished bridge south of the bascule span have been removed. All piles north of the bascule span have been removed with the exception of four piles, which are attached to the bascule span for support. The Coast Guard has reviewed Route 52 Construction's plan to move the main navigational channel 100 feet south of the most southern portion of the remaining bridge to allow vessel traffic to safely pass during the demolition of the bascule span. Once the bascule span is removed, the piles will be removed and the bridge will be completely removed from the waterway.

The removal of the remaining piles, which are secured to the sea floor bed, will be completed by using explosives, after which the piles and debris will be removed. The Captain of the Port, Delaware Bay, has determined that potential hazards associated with pile blasting and removal operations, beginning on or about October 1, 2016, will be a safety concern for anyone operating within 500 yards of pile blasting and removal operations during times of explosive detonation.

The purpose of this rule is to promote maritime safety and protect vessels from the hazards of bridge demolition and pile blasting operations, and to maintain safety of navigation in the Great Egg Harbor Bay, in the vicinity of the Route 9, Beesley Point Bridge. The rule will provide for a clear transit route for vessels, provide a safety buffer around the crane and barge while demolition operations are conducted, and provide a safety buffer around the blasting vessel during times of explosive detonation.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the final details for this event were not received by the Coast Guard until August 18, 2016, and the demolition work will begin August 22, 2016. The first safety zone is required by August 22, 2016, for the demolition of the remaining portion of the bridge, and it is impracticable to publish an NPRM and consider comments before that date. Allowing this event to go forward without a safety zone in place would expose mariners and the public to unnecessary dangers associated with bridge demolition operations. The crane and barge must be placed in the main navigational channel to facilitate the removal of the remaining portion of the bridge. Therefore, it is imperative that there is a clear transit route and safety zone around the demolition location.

Furthermore, the second safety zone is needed for blasting operations which will begin on or about October 1, 2016. It is impracticable to publish an NPRM and consider comments due to the short window of time until the operation begins. Allowing this event to go forward without a safety zone in place would expose mariners and the public to unnecessary dangers associated with pile blasting operations.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register** for the reasons we stated for not publishing an NPRM. The Coast Guard expects minimal impact to vessels transiting through the alternate channel. Vessels will be able to safely transit through the alternate channel at all times, except during times of explosive detonation. The alternate channel will have the same horizontal clearance and no vertical clearance restriction, similar to the current navigational channel. Furthermore, notification for the first safety zone will be made via marine safety broadcast using VHF–FM channel 16 and through the Local Notice to Mariners.

For the second safety zone, the pile blasting operation, two blasting events will occur on consecutive days to complete both piers. Notification for the second safety zone will be a combination of broadcast notice to mariners, local notice to mariners, posted warning signs, 500 yard marine traffic safety zone maintained by the contractor's safety boats during time of explosive detonations, a 10 minute, 5 minutes, and 1 minute warning made by the blasting vessel via VHF–FM channel 16, and warning signals at 5 minutes with 3 short blasts of the air horn, and 1 minute warning of 2 short blasts of the air horn. The schedule of the signals will be posted along with all other required company, Local, State, and Federal signage.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port, Delaware Bay has determined that potential hazards are associated with demolition and pile blasting operations of the Route 9, Beesley Point Bridge, over the Great Egg Harbor Bay, in Marmora, NJ from August 22, 2016, through October 20, 2016. The rule will provide for a clear transit route for vessels, provide a safety buffer around the crane and barge while demolition operations are conducted, and provide a safety buffer around the blasting vessel during times of explosive detonation.

The rule will minimally impact vessels transiting through the Great Egg Harbor Bay navigational channel, in the vicinity of the Route 9, Beesley Point Bridge because vessels will be able to safely transit through an adequate alternate channel, except during times of explosive detonation. The alternate channel will have the same horizontal clearance and no vertical clearance restriction, similar to the current navigational channel.

IV. Discussion of the Rule

On August 22, 2016, demolition work will begin on the remaining portion of the Route 9, Beesley Point Bridge, over the Great Egg Harbor Bay, in Marmora, NJ. The Captain of the Port, Delaware Bay, has determined that the hazards associated with demolition and pile blasting operations require two separate safety zones. The first safety zone will encompass all the navigable waters within 250 feet of the marine equipment and demolition operation. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Delaware Bay, or his designated representative. Vessels wishing to transit the waterway may navigate approximately 100 feet south of the main navigational channel to the alternate navigational channel to safely pass the demolition equipment. An adequate alternate navigational channel will be established 100 feet south of the most southern portion of the bascule span which will have the a horizontal clearance of 60 feet and an unlimited vertical clearance. The alternate navigational channel will be clearly marked with red and green buoys; during the evening the buoys will be lit with red and green lights to signify the channel. The alternate channel will have the same horizontal clearance and no vertical clearance restrictions; the State of New Jersey has marked the channel with best water for passage of vessels. Vessels are requested to contact the demolition crew via VHF–FM channel 13 or 16 to make satisfactory passing arrangement and maintain a safe speed when transiting the alternate navigational channel.

The second safety zone will be enforced starting on or about October 1, 2016, only during times of explosive detonation, and encompasses all navigable waters in the Great Egg Harbor Bay within 500 yards of vessels and machinery being used to conduct pile blasting and removal operations. The duration of the enforcement of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while explosive detonation occurs. There will be two blasting events occurring on consecutive days to complete both piers. Actual dates and times of explosive detonation will be published with a combination of broadcast notice to mariners, local notice to mariners, posted warning signs, 500 yard marine traffic safety zone maintained by the contractors safety boats, a 10 minute, 5 minutes, and 1 minute warning made by the blasting vessel via VHF–FM channel 16, and warning signals at 5 minutes with 3 short blasts of the air horn, and 1 minute warning of 2 short blasts of the air horn. The schedule of the signals will be posted along with warning signs.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Delaware Bay, or his designated representative. No vessels may transit through the safety zone during times of explosives detonation. During pile blasting explosive detonation, vessels will be required to maintain a 500-yard distance from vessels and equipment used to conduct pile blasting and removal operations. This 500 yard radius will be secured by two contractor safety boats in the adjacent waterways. For safety reasons associated with the blasting operation, during times of explosive detonation the alternate navigational channel will be closed. At all other times vessels may transit through the established alternate navigational channel approximately 100 feet south of the southernmost remaining pile of the Route 9, Beesley Point Bridge.

Signs will be posted to identify the blast area and warning signs will be posted with the schedule of the warning signals. The contractor will verify that all vessels and persons are clear of safety zone 10 minutes prior to the scheduled shot time and will remain secured until the blaster gives the "All Clear". All persons involved with securing the blast zone will be equipped with marine radios. A 10 minute, 5 minutes, and 1 minute warning made by the blasting vessel via VHF–FM channel 16, and warning signals at 5 minutes with 3 short blasts of the air horn, and 1 minute warning of 2 short blasts of the air horn. After every explosive detonation the blasting vessels will give the "All Clear" when the alternate channel is clear for vessels to transit.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This finding is based on the limited size of the zone and the availability for vessels to transit freely through the alternate channel, around the first safety zone. Vessels will only be affected during times of explosive detonation, where the second safety zone will be enforced. The second safety zone is of a limited size and duration as blasting will occur only for a consecutive two day period. In addition, the zones will be well publicized to allow mariners to make alternative plans for transiting the affected area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

It is expected that there will be minimal disruption to the maritime community. Before the effective period, the Coast Guard will issue maritime advisories widely available to users of the river to allow mariners to make alternative plans for transiting the affected areas. In addition, vessels may transit around the zone through an alternate channel, except during time of explosive detonation.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of

$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves two safety zones, the first encompassing all the waters within 250 feet of demolition operations on the remaining portion of the Route 9, Beesley Point Bridge, over Great Egg Harbor Bay, in Marmora, NJ and the second encompassing all navigable waters in the Great Egg Harbor Bay within 500 yards of vessels and machinery being used to conduct pile blasting and removal operations during times of explosive detonation. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–0665, to read as follows:

§ 165.T05–0665 Safety Zone; Great Egg Harbor Bay, Marmora, NJ.

(a) *Regulated areas.* The following areas are safety zones:

(1) *Bascule span demolition zone.* All waters within 250 feet of vessels and machinery conducting demolition operations in Great Egg Harbor Bay, in the vicinity of Route 9, Beesley Point Bridge bascule span, in Marmora, NJ.

(2) *Bridge pile blasting zone.* All waters within 500 yards of the blasting vessel and equipment conducting pile blasting operations, in Great Egg Harbor Bay, in the vicinity of Route 9, Beesley Point Bridge, in Marmora, NJ.

(b) *Regulations.* The general safety zone regulations in § 165.23 apply to the safety zones created by this temporary section, § 165.T05–0665.

(1) All vessels and persons are prohibited from entering into or moving within the safety zones described in paragraph (a) of this section while they are subject to enforcement, unless authorized by the Captain of the Port, Delaware Bay, or by his designated representative.

(2) Persons or vessels seeking to enter or pass through the safety zones must contact the Captain of the Port, Delaware Bay, or his designated representative to seek permission to transit the area. The Captain of the Port, Delaware Bay can be contacted at telephone number 215–271–4807 or on Marine Band Radio VHF Channel 16 (156.8 MHz).

(3) Vessels may freely transit through the marked alternate channel, approximately 100 feet south of the most southern portion of the bascule span. The alternate channel has a horizontal clearance of 60 feet and unlimited vertical clearance. The alternate channel will be marked with red and green buoys and the buoys will be lit at night. Vessels are requested to contact the demolition crew via VHF–FM channel 13 or 16 to make satisfactory passing arrangement and maintain a safe speed when transiting the alternate navigational channel.

(4) No vessels may transit through the safety zone described in paragraph (a)(2) of this section during times of explosives detonation. During pile blasting detonation, vessels will be required to maintain a 500 yard distance from the blasting vessel and equipment. Within the 500 yards is the alternate channel, approximately 100 feet south of the most southern portion of the bascule span. Therefore no vessel may transit the alternate channel during times of explosive detonation. Actual dates and times of explosive detonation will be announced with a combination of broadcast notice to mariners, local notice to mariners, posted warning signs, 500 yard marine traffic safety zone maintained by the contractors safety boats, 10 minute, 5 minutes, and 1 minute warning made by the blasting vessel via VHF–FM channel 16, and warning signals at 5 minutes with 3 short blasts of the air horn, and 1 minute warning of 2 short blasts of the air horn. The schedule of the signals will be posted along with all other required signage.

(5) This section applies to all vessels except those engaged in the following operations: enforcing laws, servicing aids to navigation, and emergency response vessels.

(c) *Definitions.* As used in this section:

Captain of the Port Delaware Bay means the Commander, U.S. Coast Guard Sector Delaware Bay, Philadelphia, PA.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Delaware Bay to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This first safety zone will be enforced from August 22, 2016, through October 20, 2016, unless cancelled earlier by the Captain of the Port. The second safety zone for pile blasting will only be enforced during times of explosive detonation. Pile Blasting operations are schedule to begin on or about October 1, 2016. Actual dates and times of explosive detonation will be published with a combination of broadcast notice to mariners, local notice to mariners, posted warning signs, 500 yard marine traffic safety zone maintained by the contractors safety boats, 10 minute, 5 minutes, and 1 minute warning made by the blasting vessel via VHF–FM channel 16, and warning signals at 5 minutes with 3 short blasts of the air horn, and 1 minute warning of 2 short blasts of the air horn. The schedule of the signals will be posted along with warning signs.

Dated: August 22, 2016.

Benjamin A. Cooper,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2016–20951 Filed 8–30–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0294; FRL–9951–52–Region 4]

Air Plan Approval; Alabama; Cross-State Air Pollution Rule

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving portions of the October 26, 2015, State Implementation Plan (SIP) submittal from Alabama concerning the Cross-State Air Pollution Rule (CSAPR). Under CSAPR, large electricity generating units (EGUs) in Alabama are subject to Federal Implementation Plans (FIPs) requiring the units to participate in CSAPR's federal trading program for annual emissions of nitrogen oxides (NO_X) and one of CSAPR's two federal trading programs for annual emissions of sulfur dioxide (SO_2). This action approves the incorporation into Alabama's SIP of the state's regulations requiring Alabama EGUs to participate in new CSAPR state trading programs for annual NO_X and SO_2 emissions integrated with the CSAPR federal trading programs, replacing the corresponding FIP requirements. These CSAPR state trading programs are substantively identical to the CSAPR federal trading programs except with regard to the provisions allocating emission allowances among Alabama units. EPA is approving the portions of the SIP revision concerning these CSAPR state trading programs because these portions of the SIP revision meet the requirements of the Clean Air Act (CAA or Act) and EPA's regulations for approval of a CSAPR full SIP revision replacing the requirements of a CSAPR FIP. Under the CSAPR regulations, approval of these portions of the SIP revision automatically eliminates Alabama units' obligations to participate in CSAPR's federal trading programs for annual NO_X and SO_2 emissions under the corresponding CSAPR FIPs addressing interstate transport requirements for the 1997 and 2006 Fine Particulate Matter ($PM_{2.5}$) national ambient air quality standards (NAAQS). Approval of these portions of the SIP revision fully satisfies Alabama's good neighbor obligation under the CAA to prohibit emissions which will significantly contribute to nonattainment or interfere with maintenance of the 1997 and 2006 $PM_{2.5}$ NAAQS in any other state. This approval also addresses the judicial remand of the federally-established CSAPR Phase 2 SO_2 budget for Alabama. EPA is not acting at this time on the portion of Alabama's SIP submittal intended to replace Alabama units' obligations to participate in CSAPR's federal trading program for ozone-season NO_X emissions under a separate CSAPR FIP.

DATES: This rule is effective September 30, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No EPA–R04–OAR–2016–0294. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Scofield can be reached by telephone at (404) 562–9034 or via electronic mail at *scofield.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on CSAPR and CSAPR-Related SIP revisions

EPA issued CSAPR in July 2011 to address the requirements of CAA section 110(a)(2)(D)(i)(I) concerning interstate transport of air pollution.[1] As amended, CSAPR requires 28 Eastern states to limit their statewide emissions of SO_2 and/or NO_X in order to mitigate transported air pollution unlawfully impacting other states' ability to attain or maintain three NAAQS: the 1997 ozone NAAQS, the 1997 annual $PM_{2.5}$ NAAQS, and the 2006 24-hour $PM_{2.5}$ NAAQS. The CSAPR emissions limitations are defined in terms of maximum statewide "budgets" for emissions of annual SO_2, annual NO_X, and/or ozone-season NO_X by each covered state's large EGUs. The CSAPR state budgets are implemented in two phases of generally increasing stringency, with the Phase 1 budgets applying to emissions in 2015 and 2016 and the Phase 2 budgets applying to emissions in 2017 and later years. As a mechanism for achieving compliance with the emissions limitations, CSAPR established four federal emissions trading programs: A program for annual NO_X emissions, a program for ozone-season NO_X emissions, and two geographically separate programs for annual SO_2 emissions. CSAPR also established FIP requirements applicable to the large electricity generating units in each covered state. The CSAPR FIP provisions require each state's units to participate in up to three of the four CSAPR trading programs.

CSAPR includes provisions under which states may submit and EPA will approve SIP revisions to modify or replace the CSAPR FIP requirements while allowing states to continue to meet their transport-related obligations using either CSAPR's federal emissions trading programs or state emissions trading programs integrated with the federal programs.[2] Through such a SIP revision, a state may replace EPA's default provisions for allocating emission allowances among the state's units, employing any state-selected methodology to allocate or auction the allowances, subject to timing conditions and limits on overall allowance quantities. In the case of CSAPR's federal trading program for ozone-season NO_X emissions (or an integrated state trading program), a state may also expand trading program applicability to include certain smaller electricity generating units. If a state wants to replace CSAPR FIP requirements with SIP requirements under which the state's units participate in a state trading program that is integrated with and identical to the federal trading program even as to the allocation and applicability provisions, the state may submit a SIP revision for that purpose as well. However, no emissions budget increases or other substantive changes to the trading program provisions are allowed. A state whose units are subject to multiple CSAPR FIPs and federal trading programs may submit SIP revisions to modify or replace either some or all of those FIP requirements.

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[1] Federal Implementation Plans; Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 FR 48208 (August 8, 2011) (codified as amended at 40 CFR 52.38 and 52.39 and subparts AAAAA through DDDDD of 40 CFR part 97).

[2] *See* 40 CFR 52.38, 52.39. States also retain the ability to submit SIP revisions to meet their transport-related obligations using mechanisms other than the CSAPR federal trading programs or integrated state trading programs.

States can submit two basic forms of CSAPR-related SIP revisions effective for emissions control periods in 2017 or later years.[3] Specific conditions for approval of each form of SIP revision are set forth in the CSAPR regulations. Under the first alternative—an "abbreviated" SIP revision—a state may submit a SIP revision that upon approval replaces the default allowance allocation and/or applicability provisions of a CSAPR federal trading program for the state.[4] Approval of an abbreviated SIP revision leaves the corresponding CSAPR FIP and all other provisions of the relevant federal trading program in place for the state's units.

Under the second alternative—a "full" SIP revision—a state may submit a SIP revision that upon approval replaces a CSAPR federal trading program for the state with a state trading program integrated with the federal trading program, so long as the state trading program is substantively identical to the federal trading program or does not substantively differ from the federal trading program except as discussed above with regard to the allowance allocation and/or applicability provisions.[5] For purposes of a full SIP revision, a state may either adopt state rules with complete trading program language, incorporate the federal trading program language into its state rules by reference (with appropriate conforming changes), or employ a combination of these approaches.

The CSAPR regulations identify several important consequences and limitations associated with approval of a full SIP revision. First, upon EPA's approval of a full SIP revision as correcting the deficiency in the state's implementation plan that was the basis for a particular set of CSAPR FIP requirements, the obligation to participate in the corresponding CSAPR federal trading program is automatically eliminated for units subject to the state's jurisdiction without the need for a separate EPA withdrawal action, so long as EPA's approval of the SIP is full and unconditional.[6] Second, approval of a full SIP revision does not terminate the obligation to participate in the corresponding CSAPR federal trading program for any units located in any Indian country within the borders of the state, and if and when a unit is located in Indian country within a state's borders, EPA may modify the SIP approval to exclude from the SIP, and include in the surviving CSAPR FIP instead, certain trading program provisions that apply jointly to units in the state and to units in Indian country within the state's borders.[7] Finally, if at the time a full SIP revision is approved EPA has already started recording allocations of allowances for a given control period to a state's units, the federal trading program provisions authorizing EPA to complete the process of allocating and recording allowances for that control period to those units will continue to apply, unless EPA's approval of the SIP revision provides otherwise.[8]

Certain CSAPR Phase 2 emissions budgets have been remanded to EPA for reconsideration.[9] However, the CSAPR trading programs remain in effect and all CSAPR emissions budgets likewise remain in effect pending EPA final action to address the remands. The remanded budgets include the CSAPR Phase 2 SO_2 emissions budget applicable to Alabama units under the federal CSAPR SO_2 Group 2 Trading Program.

In 2015, EPA proposed to update CSAPR to address Eastern states' interstate air pollution mitigation obligations with regard to the 2008 ozone NAAQS. Among other things, the proposed rule would amend the Phase 2 emissions budget applicable to Alabama units under the CSAPR NO_X Ozone Season Trading Program and would make technical corrections and nomenclature changes that would apply throughout the CSAPR regulations, including the CSAPR FIPs at 40 CFR part 52 and the CSAPR federal trading program regulations for annual NO_X, ozone-season NO_X, and SO_2 emissions at 40 CFR part 97.[10]

In the CSAPR rulemaking, EPA determined that air pollution transported from Alabama would unlawfully affect other states' ability to attain or maintain the 1997 and 2006 $PM_{2.5}$ NAAQS and the 1997 ozone NAAQS.[11] Alabama units meeting the CSAPR applicability criteria were consequently made subject to FIP provisions requiring participation in CSAPR federal trading programs for SO_2, annual NO_X, and ozone-season NO_X emissions.[12] On October 26, 2015, Alabama submitted to EPA a SIP revision including provisions that, if all portions were approved, would incorporate into Alabama's SIP CSAPR state trading program regulations that would replace the CSAPR regulations for all three of these federal trading programs with regard to Alabama units for control periods in 2017 and later years. In a notice of proposed rulemaking (NPRM) published on June 28, 2016 (81 FR 41914), EPA proposed to approve portions of Alabama's October 26, 2015, SIP submittal designed to replace the CSAPR federal SO_2 and annual NO_X trading programs. EPA did not propose to take action on the portion of the SIP submittal designed to replace the federal CSAPR ozone-season NO_X trading program. The NPRM provides additional detail regarding the background and rationale for EPA's action. Comments on the NPRM were due on or before July 28, 2016. EPA received no adverse comments on the proposed action.

II. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of ADEM Administrative Code rules 335–3–8–.07 through 335–3–8–.38 (establishing Alabama's "TR NO_X Annual Trading Program") and 335–3–5–.06 through 335–3–5–.36 (establishing Alabama's "TR SO_2 Group 2 Trading Program"), effective November 24, 2015.[13] Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[14] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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[3] CSAPR also provides for a third, more streamlined form of SIP revision that is effective only for control periods in 2016 and is not relevant here. *See* § 52.38(a)(3), (b)(3); § 52.39(d), (g).

[4] § 52.38(a)(4), (b)(4); § 52.39(e), (h).

[5] § 52.38(a)(5), (b)(5); § 52.39(f), (i).

[6] § 52.38(a)(6), (b)(6); § 52.39(j).

[7] § 52.38(a)(5)(iv)–(v), (a)(6), (b)(5)(v)–(vi), (b)(6); § 52.39(f)(4)–(5), (i)(4)–(5), (j).

[8] § 52.38(a)(7), (b)(7); § 52.39(k).

[9] *EME Homer City Generation, L.P.* v. *EPA*, 795 F.3d 118, 138 (D.C. Cir. 2015).

[10] 80 FR 75706, 75710, 75757 (December 3, 2015).

[11] 76 FR at 48213.

[12] 40 CFR 52.38(a)(2), (b)(2); § 52.39(c); § 52.54(a), (b); § 52.55.

[13] EPA notes that ADEM Administrative Code rules 335–3–5–.06 through 335–3–05–.08 and 335–3–05–.11 through 335–3–05–.14 (state effective November 24, 2015) for the TR SO_2 Group 2 trading program have the same numeric regulatory citations as the regulations in the SIP for Alabama's existing CAIR SO_2 trading program as identified at 40 CFR 52.50(c) and that the ADEM Administrative Code rules 335–3–8–.07 through 335–3–8–.33 (with the exception of rules 335–3–8–.15, –.19, –.22, –.28,

III. Final Actions

EPA is approving the portions of Alabama's October 26, 2015, SIP submittal concerning the establishment for Alabama units of CSAPR state trading programs for annual NO_X and SO_2 emissions for compliance periods in 2017 and later years. The revision adopts into the SIP the state trading program rules codified in ADEM Administrative Code rules 335–3–8–.07 through 335–3–8–.38 (establishing Alabama's "TR NO_X Annual Trading Program") and 335–3–5–.06 through 335–3–5–.36 (establishing Alabama's "TR SO_2 Group 2 Trading Program").[15] These Alabama CSAPR state trading programs will be integrated with the federal CSAPR NO_X Annual Trading Program and the federal CSAPR SO_2 Group 2 Trading Program, respectively, and are substantively identical to the federal trading programs except with regard to the allowance allocation provisions.[16] Following approval of these portions of the SIP revision, Alabama units therefore will generally be required to meet requirements under Alabama's CSAPR state trading programs equivalent to the requirements the units otherwise would have been required to meet under the corresponding CSAPR federal trading programs, but allocations to Alabama units of CSAPR NO_X Annual allowances for compliance periods in 2017 and later years will be determined according to the SIP's allocation provisions at Alabama rule 335–3–8–.14 instead of EPA's default allocation provisions at 40 CFR 97.411(a), 97.411(b)(1), and 97.412(a), and allocations to Alabama units of CSAPR SO_2 Group 2 allowances will be determined according to the SIP's allocation provisions at Alabama rule 335–3–5–.13 instead of EPA's default allocation provisions at 40 CFR 97.711(a), 97.711(b)(1), and 97.712(a). EPA is approving these portions of the SIP revision because they meet the requirements of the CAA and EPA's regulations for approval of a CSAPR full SIP revision replacing a federal trading program with a state trading program that is integrated with and substantively identical to the federal trading program except for permissible differences with respect to emission allowance allocation provisions.

EPA promulgated the FIP provisions requiring Alabama units to participate in the federal CSAPR NO_X Annual Trading Program and the federal CSAPR SO_2 Group 2 Trading Program in order to address Alabama's obligations under CAA section 110(a)(2)(D)(i)(I) with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS in the absence of SIP provisions addressing those requirements. Approval of the portions of Alabama's SIP submittal adopting CSAPR state trading program rules for annual NO_X and SO_2 substantively identical to the corresponding CSAPR federal trading program regulations (or differing only with respect to the allowance allocation methodology) will correct the same deficiency in the SIP that otherwise would be corrected by those CSAPR FIPs. Under the CSAPR regulations, upon EPA's full and unconditional approval of a SIP revision as correcting the SIP's deficiency that is the basis for a particular CSAPR FIP, the obligation to participate in the corresponding CSAPR federal trading program is automatically eliminated for units subject to the state's jurisdiction (but not for any units located in any Indian country within the state's borders).[17] The approval of the portions of Alabama's SIP submittal establishing CSAPR state trading program rules for annual NO_X and SO_2 emissions therefore will result in automatic termination of the obligations of Alabama units to participate in the federal CSAPR NO_X Annual Trading Program and the federal CSAPR SO_2 Group 2 Trading Program. Further, when promulgating the FIP provisions requiring Alabama units to participate in those two CSAPR trading programs, EPA found that those FIP requirements would fully satisfy Alabama's obligation pursuant to CAA section 110(a)(2)(D)(i)(I) to prohibit emissions which will significantly contribute to nonattainment or interfere with maintenance of the 1997 and 2006 $PM_{2.5}$ NAAQS in any other state.[18] This approval of portions of Alabama's SIP revision as correcting the SIP's deficiency that was the basis for those FIP requirements therefore likewise fully satisfies the state's transport obligation with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS.

As noted in EPA's NPRM, the Phase 2 SO_2 budget established for Alabama in the CSAPR rulemaking has been remanded to EPA for reconsideration.[19] With the approval of these portions of the SIP revision as proposed, Alabama has fulfilled its obligations to provide a SIP that addresses the interstate transport provisions of CAA section 110(a)(2)(D)(i)(I) with respect to the 1997 and 2006 $PM_{2.5}$ NAAQS. Thus, EPA no longer has an obligation to (nor does EPA have the authority to) address those transport requirements through implementation of a FIP, and approval of these portions of the SIP revision eliminates Alabama units' obligations to participate in the federal CSAPR NO_X Annual Trading Program and the federal CSAPR SO_2 Group 2 Trading Program. Elimination of Alabama units' obligations to participate in the federal trading programs includes elimination of the requirements to comply with the federally-established Phase 2 budgets capping allocations of CSAPR NO_X Annual allowances and CSAPR SO_2 Group 2 allowances to Alabama units under those federal trading programs.

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and –.31) (state effective November 24, 2015) for the TR NO_X Annual trading program have the same numeric regulatory citations as the regulations in the SIP for Alabama's existing NO_X Budget trading and the CAIR NO_X Annual trading programs as identified at 40 CFR 52.50(c). The existing NO_X Budget trading and CAIR regulations remain in the Alabama SIP and are not superseded by the TR regulations approved into the SIP in this final action even though these TR regulations share the same numeric citations. Therefore, the regulatory table at 40 CFR 52.50(c) retains the existing NO_X Budget and CAIR SO_2 and NO_X Annual trading programs and includes the TR SO_2 Group 2 and NO_X Annual trading programs.

[14] 62 FR 27968 (May 22, 1997).

[15] Consistent with the current CSAPR regulatory text, the Alabama rules use the terms "Transport Rule" and "TR" instead of the updated terms "Cross-State Air Pollution Rule" and "CSAPR".

[16] EPA has proposed to make certain technical corrections to the CSAPR FIP and federal trading program regulations in order to more accurately reflect EPA's intent as described in the CSAPR rulemaking and has also proposed to replace "TR" with "CSAPR" throughout the regulations (for example, "TR NO_X Annual unit" would become "CSAPR NO_X Annual unit"). *See* 80 FR 75706, 75758. Because the proposed technical corrections merely clarify and do not change EPA's interpretations, where the proposed corrections would apply to a provision incorporated by reference in the Alabama rules, EPA would interpret the Alabama rules as reflecting the corrections. Further, EPA anticipates that if the proposed nomenclature updates are finalized, the final CSAPR federal regulations would explicitly provide that terms that include "CSAPR" encompass otherwise identical terms in approved SIP revisions that include "TR".

[17] 40 CFR 52.38(a)(6); § 52.39(j); *see also* § 52.54(a)(1); § 52.55(a).

[18] *See* 76 FR 48208, 48210 (August 8, 2011).

[19] *EME Homer City Generation, L.P.* v. *EPA,* 795 F.3d 118, 138 (D.C. Cir. 2015).

As approval of these portions of the SIP revision eliminates requirements to comply with Alabama's remanded federally-established Phase 2 SO_2 budget and eliminates EPA's authority to subject units in Alabama to a FIP, it is EPA's opinion that finalization of approval of this SIP action addresses the judicial remand of Alabama's federally-established Phase 2 SO_2 budget.[20]

Large electricity generating units in Alabama are subject to additional CSAPR FIP provisions requiring them to participate in the federal CSAPR NO_X Ozone Season Trading Program. While Alabama's SIP submittal also seeks to replace the CSAPR FIP requirements addressing Alabama units' ozone-season NO_X emissions, EPA is not acting on that portion of the SIP submittal at this time. Approval of this SIP revision concerning other CSAPR trading programs has no effect on any CSAPR FIP requirements applicable to Alabama units regarding ozone-season NO_X emissions.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 31, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and it shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 16, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401 *et seq.*

Subpart B—Alabama

■ 2. Section 52.50(c) is amended by:

■ a. Adding seven new entries under "Chapter No. 335–3–5 Control of Sulfur Compound Emissions" for "335–3–5–.06", "335–3–5–.07", "335–3–5–.08", "335–3–5–.11", "335–3–5–.12", "335–3–5–.13" and "335–3–5–.14" under each existing entry for "335–3–5–.06", "335–3–5–.07", "335–3–5–.08", "335–3–5–.11", "335–3–5–.12", "335–3–5–.13" and "335–3–5–.14" in numerical and date order;

■ b. Adding in numerical order under "Chapter No. 335–3–5 Control of Sulfur Compound Emissions" new entries for "335–3–5–.09", "335–3–5–.10", and "335–3–5–.15" through "335–3–5–.36";

■ c. Revising the title to Chapter No. 335–3–8;

■ d. Adding 21 new entries under "Chapter No. 335–3–8 Control of Nitrogen Oxides Emissions" for "335–3–8–.07", "335–3–8–.08", "335–3–8–.09", "335–3–8–.10", "335–3–8–.11", "335–3–8–.12", "335–3–8–.13", "335–3–8–.14", "335–3–8–.16", "335–3–8–.17", "335–3–8–.18", "335–3–8–.20", "335–3–8–.21", "335–3–8–.23", "335–3–8–.24", "335–3–8–.25", "335–3–8–.26", "335–3–8–.27", "335–3–8–.29", "335–3–8–.30" and "335–3–8–.33", under each existing entry for "335–3–8–.07", "335–3–8–.08", "335–3–8–.09", "335–3–8–.10", "335–3–8–.11", "335–3–8–.12", "335–3–8–.13", "335–3–8–.14", "335–3–8–.16", "335–3–8–.17", "335–3–8–.18", "335–3–8–.20", "335–3–8–.21", "335–3–8–.23", "335–3–8–.24", "335–3–8–.25", "335–3–8–.26", "335–3–8–.27", "335–3–8–.29", "335–

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[20] Although the court in *EME Homer City Generation* remanded Alabama's Phase 2 SO_2 budget because it determined that the budget was too stringent, nothing in the court's decision affects Alabama's authority to seek incorporation into its SIP of a state-established budget as stringent as the remanded federally-established budget or limits EPA's authority to approve such a SIP revision. *See* 42 U.S.C. 7416, 7410(k)(3).

3–8–.30" and "335–3–8–.33", in numerical and date order; and

■ e. Adding in numerical order under "Chapter No. 335–3–8 Control of Nitrogen Oxides Emissions" new entries for "335–3–8–.15", "335–3–8–.19", "335–3–8–.22", "335–3–8–.28", "335–3–8–.31", "335–3–8–.34", "335–3–8–.35", "335–3–8–.36", "335–3–8–.37" and "335–3–8–.38".

The additions and revision read as follows:

§ 52.50 Identification of plan.

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(c) * * *

EPA APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter No. 335–3–5 Control of Sulfur Compound Emissions				
*	*	*	*	*
Section 335–3–5–.06.	TR SO_2 Trading Program—Purpose and Definitions.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.06 are included in the approved SIP.
*	*	*	*	*
Section 335–3–5–.07.	TR SO_2 Trading Program—Applicability	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.07 are included in the approved SIP.
*	*	*	*	*
Section 335–3–5–.08.	TR SO_2 Trading Program—Retired Unit Exemption.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.08 are included in the approved SIP.
Section 335–3–5–.09.	TR SO_2 Trading Program—Standard Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.10.	TR SO_2 Trading Program—omputation of Time.	11/24/2015	8/31/2016 [Insert citation of publication].	
*	*	*	*	*
Section 335–3–5–.11.	Administrative Appeal Procedures	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.11 are included in the approved SIP.
*	*	*	*	*
Section 335–3–5–.12.	SO_2 Trading Budgets and Variability Limits.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.12 are included in the approved SIP.
*	*	*	*	*
Section 335–3–5–.13.	TR SO_2 Allowance Allocations	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.13 are included in the approved SIP.
*	*	*	*	*
Section 335–3–5–.14.	Authorization of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–5–.14 are included in the approved SIP.
Section 335–3–5–.15.	Responsibilities of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.16.	Changing Designated Representative and Alternate Designated Representative; Changes in Owners and Operators; Changes in Units at the Source.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.17.	Certificate of Representation	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.18.	Objections Concerning Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.19.	Delegation by Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–5–.20.	Reserved	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.21.	Establishment of Compliance Accounts, Assurance Accounts, and General Accounts.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.22.	Recordation of TR SO_2 Allowance Allocations and Auction Results.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.23.	Submission of TR SO_2 Allowance Transfers.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.24.	Recordation of TR SO_2 Allowance Transfers.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.25.	Compliance with TR SO_2 Emissions Limitation.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.26.	Compliance with TR SO_2 Assurance Provisions.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.27.	Banking	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.28.	Account Error	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.29.	Administrator's Action on Submissions	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.30.	Reserved	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.31.	General Monitoring, Recordkeeping, and Reporting Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.32.	Initial Monitoring System Certification and Recertification Procedures.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.33.	Monitoring System Out-of-Control Periods.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.34.	Notifications Concerning Monitoring	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.35.	Recordkeeping and Reporting	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–5–.36.	Petitions for Alternatives to Monitoring, Recordkeeping, or Reporting Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	
*	*	*	*	* * *
Chapter No. 335–3–8 Control of Nitrogen Oxides Emissions				
*	*	*	*	* * *
Section 335–3–8–.07.	TR NO_X Annual Trading Program—Purpose and Definitions.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.07 are included in the approved SIP.
*	*	*	*	* * *
Section 335–3–8–.08.	TR NO_X Annual Trading Program—Applicability.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.08 are included in the approved SIP.
*	*	*	*	* * *
Section 335–3–8–.09.	TR NO_X Annual Trading Program—Retired Unit Exemption.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.09 are included in the approved SIP.

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
* * * * * * *				
Section 335–3–8–.10.	TR NO_X Annual Trading Program—Standard Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.10 are included in the approved SIP.
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Section 335–3–8–.11.	TR NO_X Annual Trading Program—Computation of Time.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.11 are included in the approved SIP.
* * * * * * *				
Section 335–3–8–.12.	Administrative Appeal Procedures	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.12 are included in the approved SIP.
* * * * * * *				
Section 335–3–8–.13.	NO_X Annual Trading Budgets and Variability Limits.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.13 are included in the approved SIP.
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Section 335–3–8–.14.	TR NO_X Annual Allowance Allocations	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.14 are included in the approved SIP.
Section 335–3–8–.15.	Reserved	11/24/2015	8/31/2016 [Insert citation of publication].	
* * * * * * *				
Section 335–3–8–.16.	Authorization of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.16 are included in the approved SIP.
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Section 335–3–8–.17.	Responsibilities of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.17 are included in the approved SIP.
* * * * * * *				
Section 335–3–8–.18.	Changing Designated Representative and Alternate Designated Representative; Changes in Owners and Operators; Changes in Units at the Source.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.18 are included in the approved SIP.
Section 335–3–8–.19.	Certificate of Representation	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.19 are included in the approved SIP.
* * * * * * *				
Section 335–3–8–.20.	Objections Concerning Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.20 are included in the approved SIP.
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Section 335–3–8–.21.	Delegation by Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.21 are included in the approved SIP.
Section 335–3–8–.22.	Reserved	11/24/2015	8/31/2016 [Insert citation of publication].	
* * * * * * *				
Section 335–3–8–.23.	Establishment of Compliance Accounts, Assurance Accounts, and General Accounts.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.23 are included in the approved SIP.
* * * * * * *				
Section 335–3–8–.24.	Recordation of TR NO_X Annual Allowance Allocations and Auction Results.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.24 are included in the approved SIP.

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Section 335–3–8–.25.	Submission of TR NO$_X$ Annual Allowance Transfers.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.25 are included in the approved SIP.
*	*	*	*	*
Section 335–3–8–.26.	Recordation of TR NO$_X$ Annual Allowance Transfers.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.26 are included in the approved SIP.
*	*	*	*	*
Section 335–3–8–.27.	Compliance with TR NO$_X$ Annual Emissions Limitation.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.27 are included in the approved SIP.
Section 335–3–8–.28.	Compliance with TR NO$_X$ Annual Assurance Provisions.	11/24/2015	8/31/2016 [Insert citation of publication].	
*	*	*	*	*
Section 335–3–8–.29.	Banking	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.297 are included in the approved SIP.
*	*	*	*	*
Section 335–3–8–.30.	Account Error	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.30 are included in the approved SIP.
Section 335–3–8–.31.	Administrator's Action on Submissions	11/24/2015	8/31/2016 [Insert citation of publication].	
*	*	*	*	*
Section 335–3–8–.33.	General Monitoring, Recordkeeping, and Reporting Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	Both sections of 335–3–8–.33 are included in the approved SIP.
Section 335–3–8–.34.	Initial Monitoring System Certification and Recertification Procedures.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–8–.35.	Monitoring System Out-of-Control Periods.	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–8–.36.	Notifications Concerning Monitoring	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–8–.37.	Recordkeeping and Reporting	11/24/2015	8/31/2016 [Insert citation of publication].	
Section 335–3–8–.38.	Petitions for Alternatives to Monitoring, Recordkeeping, or Reporting Requirements.	11/24/2015	8/31/2016 [Insert citation of publication].	
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[FR Doc. 2016–20854 Filed 8–30–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0636; FRL–9951–42–Region 9]

Approval and Promulgation of Air Quality State Implementation Plans; California; San Joaquin Valley; Moderate Area Plan for the 2006 PM$_{2.5}$ NAAQS

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of the state implementation plan revisions (SIP) submitted by California to address Clean Air Act requirements for the 2006 fine particulate matter (PM$_{2.5}$) National Ambient Air Quality Standards in the San Joaquin Valley Moderate PM$_{2.5}$ nonattainment area. These SIP revisions are the 2012 PM$_{2.5}$ Plan, submitted March 4, 2013, the 2014 Supplement, submitted November 6, 2014, and the

motor vehicle emission budgets for the 2006 $PM_{2.5}$ NAAQS submitted November 13, 2015. The EPA is disapproving interpollutant trading ratios identified in the SIP submission for nonattainment new source review permitting purposes because the ratios are not supported by a sufficient technical demonstration.

DATES: This rule is effective on September 30, 2016.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2014–0636. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, EPA Region 9, (415) 947–4192, *tax.wienke@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

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I. Background

A. Proposed Action

On January 13, 2015, we proposed to approve SIP revisions submitted by California to address Clean Air Act (CAA or "the Act") requirements for the 2006 primary and secondary 24-hour $PM_{2.5}$ national ambient air quality standards (NAAQS or "standards") in the San Joaquin Valley (SJV) $PM_{2.5}$ nonattainment area.[1] These SIP revisions are the 2012 $PM_{2.5}$ Plan, submitted March 4, 2013, and the "Supplemental Document, Clean Air Act Subpart 4: The 2012 $PM_{2.5}$ Plan for the 2006 $PM_{2.5}$ Standard, and District Rule 2201 (New and Modified Stationary Source Review)" (2014 Supplement), submitted November 6, 2014. We also proposed to approve, through parallel processing, the proposed motor vehicle emissions budgets (MVEBs) for the 2006 $PM_{2.5}$ NAAQS submitted on November 6, 2014, which California submitted in final form on December 29, 2014, and the related trading mechanism for transportation conformity purposes. We refer to these submissions collectively herein as "the 2012 $PM_{2.5}$ Plan" or simply "the Plan."

The EPA proposed to approve the following elements of the 2012 $PM_{2.5}$ Plan as satisfying applicable CAA requirements: (1) The 2007 base year emissions inventories, (2) the demonstration that attainment by the Moderate area attainment date of December 31, 2015 is impracticable, (3) the reasonably available control measures/reasonably available control technology (RACM/RACT) demonstration, (4) the reasonable further progress (RFP) demonstration, (5) the San Joaquin Valley Unified Air Pollution Control District's (SJVUAPCD's or "District's") commitments to adopt and implement specific rules and measures by specific dates, and (6) the 2014 and 2017 MVEBs for direct $PM_{2.5}$ and oxides of nitrogen (NO_X). The EPA also proposed to determine that volatile organic compounds (VOC) emissions do not contribute significantly to ambient $PM_{2.5}$ levels that exceed the 2006 $PM_{2.5}$ NAAQS in the SJV but to find the State's and District's demonstration concerning ammonia emissions insufficient to rebut the regulatory presumption for ammonia.

The EPA proposed to disapprove interpollutant trading ratios identified in these SIP submittals for nonattainment new source review (NNSR) permitting purposes. Finally, the EPA proposed to reclassify the SJV area, including Indian country within it, as a Serious nonattainment area for the 2006 $PM_{2.5}$ NAAQS, based on the EPA's determination that the area could not practicably attain these standards by the applicable Moderate area attainment date of December 31, 2015.

B. Final Reclassification of the SJV Area From Moderate to Serious for the 2006 $PM_{2.5}$ NAAQS

On December 22, 2015, we finalized our January 13, 2015 proposal to reclassify the SJV area from Moderate to Serious for the 2006 $PM_{2.5}$ NAAQS.[2] As a result of that action, by August 21, 2017, California is required to submit additional SIP revisions to satisfy the statutory requirements that apply to Serious $PM_{2.5}$ nonattainment areas, including the requirements of subpart 4 of part D, title I of the Act. The Serious area plan must provide for attainment of the 2006 $PM_{2.5}$ NAAQS in the SJV area as expeditiously as practicable, but no later than December 31, 2019, in accordance with the requirements of part D of title I of the Act.

C. Motor Vehicle Emissions Budgets in the 2012 $PM_{2.5}$ Plan

As part of our January 13, 2015 proposed action, we proposed to approve the proposed 2014 and 2017 MVEBs for the 2006 $PM_{2.5}$ NAAQS submitted by the California Air Resources Board (CARB) on November 6, 2014 with a request for parallel processing. CARB formally submitted the final budgets to the EPA on December 29, 2014.[3] On April 1, 2016, we found the NO_X and direct $PM_{2.5}$ budgets in the 2012 $PM_{2.5}$ Plan and 2014 Supplement, as submitted December 29, 2014, to be adequate for conformity purposes.[4] On November 13, 2015, CARB submitted a SIP revision to replace several previously-submitted MVEBs developed using EMFAC2011 with revised MVEBs developed using EMFAC2014.[5]

On May 18, 2016, we proposed to approve the revised MVEBs submitted on November 13, 2015, which address the 1997 8-hour ozone standards, the 2006 $PM_{2.5}$ standards, and the 1987 coarse particulate matter (PM_{10}) standard for the SJV area.[6] We received no public comments on this proposal. Today, we are finalizing action only on the revised 2017 MVEBs addressing the 2006 $PM_{2.5}$ NAAQS in the SJV, as submitted November 13, 2015.[7] These NO_X and direct $PM_{2.5}$ budgets were revised using EMFAC2014, the most recent version of California's motor vehicle emission factor model approved by the EPA for use in SIPs and conformity analyses.[8] The revised budgets, presented in Table 1 below, were developed in consultation with the

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[1] 80 FR 1816 (January 13, 2015).

[2] 81 FR 2993 (January 20, 2016) (final rule) and 81 FR 42263 (June 29, 2016) (correcting amendment).

[3] Letter dated December 29, 2014, from Richard W. Corey, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region 9, with enclosures.

[4] Letter dated April 1, 2016, from Deborah Jordan, Director, Air Division, EPA Region 9, to Richard W. Corey, Executive Officer, CARB, and 81 FR 22194 (April 15, 2016).

[5] Letter dated November 13, 2015, from Richard W. Corey, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region 9, with enclosures.

[6] 81 FR 31212 (May 18, 2016).

[7] The EPA took final action on the revised ozone and PM_{10} budgets at 81 FR 53294 (August 12, 2016). Although the 2012 $PM_{2.5}$ Plan contained MVEBs for both 2014 and 2017, MVEBs for 2014 are no longer relevant for conformity analyses since that year has passed.

[8] 80 FR 77337 (December 14, 2015).

SJVUAPCD, the eight SJV metropolitan planning organizations (MPOs), the EPA and CARB. These budgets replace the NO_X and direct $PM_{2.5}$ budgets submitted on December 29, 2014.

TABLE 1—SAN JOAQUIN VALLEY REVISED BUDGETS DEVELOPED USING EMFAC2014

County	2017 (tons per winter day)	
	$PM_{2.5}$	NO_X
Fresno	1.0	32.1
Kern (SJV)	0.8	28.8
Kings	0.2	5.9
Madera	0.2	6.0
Merced	0.3	11.0
San Joaquin	0.6	15.5
Stanislaus	0.4	12.3
Tulare	0.4	11.2

Note: CARB calculated the revised $PM_{2.5}$ budgets by taking the sum of the county-by-county emissions results from EMFAC and rounding the SJV-wide total up to the nearest whole ton for NO_X and to the nearest tenth of a ton for direct $PM_{2.5}$, then reallocating to the individual counties based on the ratio of each county's contribution to the total, and then rounding each county's emissions to the nearest tenth of a ton using the conventional rounding method. The existing adequate $PM_{2.5}$ budgets submitted December 29, 2014 were calculated in the same manner.

As part of our January 13, 2015 proposed action, the EPA also proposed to approve, in accordance with 40 CFR 93.124, the trading mechanism as described on p. C–32 in Appendix C of the 2012 $PM_{2.5}$ Plan as an enforceable component of the transportation conformity program for the SJV for the 2006 $PM_{2.5}$ NAAQS, with the condition that trades are limited to substituting excess reductions in NO_X for increases in $PM_{2.5}$. This trading mechanism was not revised by the November 13, 2015 MVEB submittal.[9] We are finalizing our proposal to approve the trading mechanism identified in the Plan for transportation conformity purposes.

The budgets that the EPA is approving herein relate to the 2006 $PM_{2.5}$ NAAQS only, and our approval of them does not affect the status of the previously-approved MVEBs for the 1997 $PM_{2.5}$ NAAQS and related trading mechanism, which remain in effect for that $PM_{2.5}$ NAAQS.

II. Public Comments and the EPA's Responses

The EPA provided a 45-day period for the public to comment on our proposed rule. During this comment period, which ended on February 27, 2015, we received two sets of public comments, one from the SJVUAPCD and another from Earthjustice on behalf of the Central Valley Air Quality Coalition, Greenaction, the Association of Irritated Residents, the Sierra Club—Tehipite Chapter, and Global Community Monitor (Earthjustice).[10] Copies of these comment letters can be found in the docket.

In our December 22, 2015 final action to reclassify the SJV area as a "Serious" $PM_{2.5}$ nonattainment area, we summarized and responded to public comments pertaining to the reclassification and its consequences and stated that we would, in a separate rulemaking, respond to comments pertaining to our proposed action on the submitted plan.[11] In our April 15, 2016 notice of adequacy, we responded to a public comment pertaining to the adequacy of the budgets.[12]

We summarize below and provide our responses to all remaining public comments on our proposed action on the 2012 $PM_{2.5}$ Plan.

A. Comment Regarding Emissions Inventories

Comment 1: Earthjustice comments on the importance of emissions inventories, noting that CAA section 172(c)(3) requires that nonattainment plans "include a comprehensive, *accurate, current* inventory of actual emissions from all sources of the relevant pollutant or pollutants in such area" (emphasis by commenter). Earthjustice argues that the EPA's proposed determination that the 2012 $PM_{2.5}$ inventories "are based on the most current and accurate information available to the State and District at the time the Plan and its inventories were being developed," does not satisfy the requirements of section 172(c)(3) that the inventory be accurate and current. While acknowledging that it is unaware of information calling into question the inventories used in the Plan, Earthjustice asserts that the EPA must take further steps to confirm that the inventories "are" (*i.e.*, remain) current and accurate before it approves the inventories. Citing *Sierra Club* v. *United States EPA*, 671 F.3d 955, 968 (9th Cir. 2012), Earthjustice states that the EPA's failure to confirm that the inventories are current and accurate "undermines the rational basis for the approval."

Response 1: The EPA does not dispute the importance of emissions inventories. We evaluated the emissions inventories in the 2012 $PM_{2.5}$ Plan to determine whether they satisfy the requirements of CAA section 172(c)(3) and adequately support the Plan's RACM, RFP, and impracticability demonstrations. Based on this evaluation, we have concluded that the Plan's 2007 base year emissions inventory was based on the most current and accurate information available to the State and District at the time the Plan was developed and submitted, and that it comprehensively addresses all source categories in the SJV area, consistent with applicable CAA requirements and EPA guidance.[13]

CAA section 172(b) provides that a state containing a nonattainment area shall submit a plan or plan revision (including the plan items) meeting the applicable requirements of CAA section 172(c) and section 110 on the schedule established by the EPA. Section 172(c) contains, inter alia, the requirement that nonattainment area plans include a "comprehensive, accurate, current inventory" of actual emissions from all sources of the relevant pollutant or pollutants in the area. We believe it is reasonable to read these provisions together as requiring that the state submit an inventory that is comprehensive, accurate, and current at the time the state submitted it to the EPA, rather than requiring that the state continually revise its plan as new emissions data become available.[14] Air quality planning is an iterative process and states and the EPA must rely on the best available data at the time the plans are created. Nothing in the *Sierra Club* decision cited by the commenters (671 F.3d 955, 9th Cir. 2012) compels the EPA to alter this longstanding interpretation of the CAA.[15]

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[9] 81 FR 31212, 31218 (May 18, 2016).

[10] *See* letter dated February 27, 2015 from Sheraz Gill, Director of Strategies and Incentives at SJVAPCD, to Wienke Tax, EPA Region 9, "Re: Docket No. EPA–R09–OAR–2014–0636, Comments on Proposed Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; California; San Joaquin Valley Moderate Area Plan and Reclassification as Serious Nonattainment for the 2006 $PM_{2.5}$ NAAQS," and letter dated February 27, 2015 from Paul Cort and Adenike Adeyeye, Earthjustice, to Ms. Wienke Tax, Air Planning Office, EPA Region 9.

[11] 81 FR 2993 (January 20, 2016).

[12] 81 FR 22194 (April 15, 2016).

[13] 80 FR 1816 at 1819–1820; *see also* "General Preamble for Implementation of Title I of the Clean Air Act Amendments of 1990," 57 FR 13498, 13502 (April 16, 1992) ("General Preamble").

[14] EPA, Office of Transportation and Air Quality (OTAQ), "Policy Guidance on the Use of MOVES2010 for State Implementation Plan Development, Transportation Conformity, and Other Purposes," December 2009; *see also* Memorandum from John Seitz, EPA, Office of Air Quality Planning and Standards and Margo Oge, OTAQ, "Policy Guidance on the Use of MOBILE6 for SIP Development and Transportation Conformity," January 18, 2002.

[15] In *Sierra Club* v. *EPA*, 671 F.3d 955 (9th Cir. 2012), the Ninth Circuit remanded the EPA's final action approving an ozone plan for the SJV on the ground that the EPA's failure to consider new inventory data submitted by CARB long before the EPA's action on the plan was arbitrary and capricious under the Administrative Procedure Act. *See* 671 F.3d at 966 ("EPA stands on shaky legal

B. Comments Regarding Precursors

Comment 2: The SJVUAPCD argues that ammonia is not a significant precursor for $PM_{2.5}$ and that additional ammonia controls are not required. The District asserts that the EPA's proposal to reject these findings is based on "technical assertions not supported by the extensive scientific research and modeling" conducted for the Plan, and that the technical analyses in the Plan demonstrate that ammonia reductions are ineffective for attaining the $PM_{2.5}$ NAAQS. Although the District recognizes that ammonia is an integral component of ammonium nitrate, which contributes substantially to wintertime $PM_{2.5}$ mass in the SJV, it argues that its scientific evaluations in the Plan provide "sufficient substantiation that controls on ammonia are known to be very insensitive to reducing ammonium nitrate mass concentrations." The District also comments that the EPA did not provide references or support for statements in its technical support document that "a detailed evaluation of the modeling shows that ammonia controls can be effective at reducing ambient $PM_{2.5}$ in some locations," and that "[i]n the various studies, when ammonia emissions were reduced by up to 50 percent, ambient ammonium nitrate decreased by 5 to 25 percent, depending on the episode modeled and the geographic location evaluated . . . . These percentages for ammonia benefits are generally smaller than those for NO_X reductions, but these modeling results show that reductions in ammonia emissions under certain circumstances can effectively reduce ambient $PM_{2.5}$" (internal citations omitted). The District argues that these statements are contrary to the Plan's Weight of Evidence Analysis in Appendix G of the 2012 $PM_{2.5}$ Plan.

Response 2: We disagree with the District's claim that we did not provide support for our conclusions about ammonia impacts in the SJV. As stated on pg. 56 of the EPA's technical support document (TSD) for the proposed rule (hereafter "Proposal TSD"),[16] the EPA's conclusion that ammonia controls can be effective at reducing ambient $PM_{2.5}$ in some locations in the SJV is based on (1) sensitivity to ammonia reductions in the air quality modeling and Weight of Evidence Analysis in the 2012 $PM_{2.5}$ Plan, (2) a number of peer-reviewed journal papers cited in the Plan showing ammonium nitrate reductions of up to 25 percent when ammonia emissions are reduced by 50 percent, and (3) the severity of $PM_{2.5}$ nonattainment in the area.[17]

Comment 3: The SJVUAPCD recognizes that ammonia is a large component of ammonium nitrate and that ammonium nitrate contributes substantially to wintertime $PM_{2.5}$ mass, but asserts that this does not necessarily mean that reductions in ammonia emissions are effective in reducing $PM_{2.5}$ concentrations in the SJV. Similarly, the District acknowledges that ammonia is found in the SJV at higher wintertime concentrations than NO_X but states that ammonia's physical abundance does not solely determine its significance as a precursor. The District cites language in the EPA's Proposal TSD stating that the EPA reviews a determination to exclude a $PM_{2.5}$ precursor by considering both "the magnitude of the precursor's contribution to ambient $PM_{2.5}$ concentrations" and "the sensitivity of ambient $PM_{2.5}$ concentrations in the area to reductions in emissions of that precursor." The District interprets this language to establish two necessary elements for precursor significance: (1) A "relatively high contribution" to overall $PM_{2.5}$ mass, and (2) availability of control mechanisms for the precursor that demonstrate a "reasonable rather than negligible" reduction in $PM_{2.5}$ mass. The District asserts that $PM_{2.5}$ concentrations in the SJV are highly insensitive to ammonia controls, particularly when compared to alternative controls on NO_X, which it claims is the limiting precursor for ammonia nitrate formation. While the District agrees with the EPA that the decision of whether to require reductions of a precursor should not be based solely on the control effectiveness of the precursor relative to other precursors, the District comments that an "additional key issue that must also be taken under consideration is the development and implementation of effective emission reductions strategies for reducing ambient $PM_{2.5}$ and bringing the [SJV] into attainment."

Response 3: The EPA generally agrees with the District's statement that both the contribution of a precursor to $PM_{2.5}$ concentrations in the area and the area's sensitivity to reductions in emissions of the precursor may be relevant for assessing the level of contribution of a $PM_{2.5}$ precursor to ambient $PM_{2.5}$ levels. The EPA also agrees with the District's conclusion that ambient $PM_{2.5}$ concentrations are more sensitive to NO_X emission reductions than to ammonia emission reductions. We disagree, however, with the District's suggestion that the effectiveness of reductions of a particular precursor in improving $PM_{2.5}$ air quality relative to a different precursor may support a conclusion that a given precursor does not contribute significantly to ambient $PM_{2.5}$ levels that exceed the NAAQS. We also disagree with the District's suggestion that the "availability of control mechanisms for the precursor that demonstrate a 'reasonable rather than negligible' reduction in $PM_{2.5}$ mass" is a necessary consideration in determining whether a particular $PM_{2.5}$ precursor is subject to control evaluation under subpart 4.

As explained in our proposed rule, ammonia is a precursor to the formation of $PM_{2.5}$ and is, therefore, presumptively regulated under subpart 4 of part D, title I of the Act.[18] Thus, CARB and the District must evaluate ammonia emissions for potential controls unless the State submits a demonstration adequate to rebut the regulatory presumption in the SJV area. The pertinent question in a demonstration to rebut the regulatory presumption for ammonia is whether ammonia emission sources "contribute significantly" to $PM_{2.5}$ levels that exceed the $PM_{2.5}$ NAAQS in the SJV, not whether existing emission control measures can achieve a specified amount of emission reductions in the area or how effective ammonia reductions are compared to reductions of other $PM_{2.5}$ precursors.[19] More specifically, with respect to the sensitivity-based contribution analysis, the pertinent question is whether $PM_{2.5}$ concentrations in the nonattainment area are "insensitive" to emissions reductions of the precursor.[20] We note that the EPA may, in some cases, require a state to identify and evaluate potential control measures to reduce emissions of a particular $PM_{2.5}$ precursor from existing sources *as part of* a sensitivity-based contribution analysis, *i.e.*, in order to adequately demonstrate that regulation of the precursor would not

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ground relying on significantly outdated data, given the amount of time that EMFAC2007 was available and authorized for use before the EPA approved the 2004 SIP"). The decision did not disturb the EPA's longstanding policy of requiring states to use the most current emissions estimate models available at the time of SIP development.

[16] EPA, Region 9, Air Division, Technical Support Document, "Proposed Action on the San Joaquin Valley 2012 $PM_{2.5}$ State Implementation Plan and 2014 Supplemental Document and Proposed Reclassification of the San Joaquin Valley as Serious Nonattainment for the 2006 $PM_{2.5}$ Standard," December 2014 ["Proposal TSD"].

[17] *Id.* at p. 56.

[18] 80 FR 1816, 1821 (January 13, 2015) (citing *NRDC* v. *EPA*, 706 F.3d 428 (D.C. Cir. 2013)).

[19] CAA section 189(e).

[20] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at Section III.C.3.d, pp. 50–54 (discussing technical issues associated with sensitivity-based contribution analysis).

provide meaningful improvements in ambient air quality.[21]

Given the severity of $PM_{2.5}$ nonattainment in the SJV area, the ambient contribution of ammonia emissions, the area's demonstrated sensitivity to ammonia control,[22] and our finding that the precursor demonstration in the Plan is insufficient to rebut the regulatory presumption for ammonia, we conclude that ammonia emissions contribute significantly to ambient $PM_{2.5}$ levels that exceed the $PM_{2.5}$ NAAQS in the SJV area and that the 2012 $PM_{2.5}$ Plan must, therefore, contain an evaluation of potential ammonia controls.

Comment 4: Earthjustice challenges the EPA's method for identifying $PM_{2.5}$ precursors subject to regulation by the Plan. Specifically, Earthjustice objects to the EPA's consideration of "both the magnitude of the precursor's contribution to ambient $PM_{2.5}$ concentrations in the nonattainment areas and the sensitivity of ambient $PM_{2.5}$ concentrations in the area to reductions in emissions of that precursor." Earthjustice argues that this language differs from CAA section 189(e), which provides that control requirements shall apply to major stationary sources of particulate matter (PM) precursors unless the EPA finds that these sources "do not contribute significantly to PM–10 levels which exceed the standard in the area." Thus, according to Earthjustice, "the statute allows for consideration only of the significance of the contribution" and does not allow for consideration of the effectiveness of controls in determining whether a precursor must be subject to control.

Earthjustice also characterizes the EPA's consideration of the sensitivity of ambient concentrations to precursor emissions reductions as a "bad" policy assessment and argues that "looking merely at the sensitivity ratios ignores the fact that pollutants like ammonia have been historically under-regulated and very well may represent the cheapest opportunities for emission reductions." Earthjustice argues that even if much larger amounts of ammonia reductions would be required to achieve the benefits of a few tons of NO_X reductions, ammonia controls may still be the "best" policy option because incremental NO_X emissions, which have already been heavily regulated, may be much more expensive. Earthjustice claims that the EPA's sensitivity test is a policy-based test but that it is not a rational policy test, because it does not consider the full regulatory context. According to Earthjustice, "decisions on how to balance controls on sources of ammonia versus sources of NO_X are for the control strategy of the Plan," and that if additional reductions beyond those achieved through the required RACM or BACM controls are necessary, "that is where the 'effectiveness' of the controls can and should be considered—not in the determination of whether a pollutant is a precursor subject to control under the Act."

Earthjustice states that the EPA has correctly proposed to determine that ammonia emissions "contribute significantly" to $PM_{2.5}$ nonattainment in the SJV given that ammonium nitrate is the largest component of the Valley's $PM_{2.5}$ levels. Thus, according to Earthjustice, ammonia controls are mandated under CAA section 189(e) regardless of the relative sensitivity of ambient concentrations to emission reductions.

Response 4: We disagree with the commenter's characterization of the legal test for determining whether or not a particular $PM_{2.5}$ precursor must be subject to control evaluation. With respect to ammonia emissions, however, this issue does not affect our action on the 2012 $PM_{2.5}$ Plan because the EPA is not determining that ammonia emission sources "do not contribute significantly" to $PM_{2.5}$ levels that exceed the 2006 $PM_{2.5}$ NAAQS in the SJV area. Instead, the EPA has concluded that the State's and District's demonstration concerning ammonia emissions in the 2012 $PM_{2.5}$ Plan and 2014 Supplement is insufficient to rebut the regulatory presumption under subpart 4 and that ammonia is, therefore, a $PM_{2.5}$ precursor subject to control evaluation for purposes of attaining the 2006 $PM_{2.5}$ NAAQS in the SJV.

As explained in our proposed rule, section 189(e) of the Act requires that the control requirements for major stationary sources of direct PM_{10} also apply to major stationary sources of PM_{10} precursors, except where the Administrator determines that such sources do not contribute significantly to PM_{10} levels that exceed the standard in the area. Section 189(e) contains the only express exception to the control requirements under subpart 4 (*e.g.,* requirements for RACM and RACT, best available control measures (BACM) and best available control technology (BACT), most stringent measures, and NSR) for sources of direct $PM_{2.5}$ and $PM_{2.5}$ precursor emissions. Although section 189(e) explicitly addresses only major stationary sources, the EPA interprets the Act as authorizing it also to determine, under appropriate circumstances, that regulation of specific $PM_{2.5}$ precursors from other source categories in a given nonattainment area is not necessary. For example, under the EPA's longstanding interpretation of the control requirements that apply to stationary, area, and mobile sources of PM_{10} precursors area-wide under CAA section 172(c)(1) and subpart 4 (*see* General Preamble, 57 FR 13498 at 13539–42), a state may demonstrate in a SIP submittal that control of a certain precursor pollutant is not necessary in light of its insignificant contribution to PM_{10} levels in the nonattainment area.[23]

We evaluated the SJV $PM_{2.5}$ Plan in accordance with the presumption embodied within subpart 4 that all $PM_{2.5}$ precursors must be addressed in the state's evaluation of potential control measures, unless the state adequately demonstrates that emissions of a particular precursor do not "contribute significantly" to ambient $PM_{2.5}$ levels that exceed the $PM_{2.5}$ NAAQS in the nonattainment area. Both the magnitude of a precursor's contribution to ambient $PM_{2.5}$ concentrations in the nonattainment area and the sensitivity of ambient $PM_{2.5}$ concentrations in the area to reductions in emissions of that precursor may be relevant to an assessment of whether the precursor contributes significantly to ambient $PM_{2.5}$ levels that exceed the $PM_{2.5}$ NAAQS in the area. As explained in the preamble to the EPA's July 29, 2016 final rule to implement the $PM_{2.5}$ NAAQS:

> The EPA . . . believes that a sensitivity-based contribution analysis is consistent with the language and intent of CAA section 189(e). As applied to attainment plans, CAA section 189(e) allows states to evaluate whether $PM_{2.5}$ precursors significantly

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[21] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at 40 CFR 51.1009(a)(2)(ii). Although this regulatory text is not yet effective, it reflects the EPA's interpretation of the statutory requirements. *See also* EPA, Response to Comments on the Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements, July 29, 2016, at p. 23 (noting that "while a valid sensitivity-based precursor demonstration generally will not require an evaluation of available controls, the EPA may determine, based on the facts and circumstances of the area, that the state needs to conduct a control measure evaluation for the relevant precursor to adequately demonstrate that regulation of the precursor would not provide meaningful reductions in ambient air quality").

[22] Proposal TSD at p. 57; *see also* 80 FR 1816, 1825 (January 13, 2015).

[23] 80 FR 1816, 1821–1822 (January 13, 2015). Courts have upheld this approach to the requirements of subpart 4 for PM_{10}. *See, e.g., Assoc. of Irritated Residents* v. *EPA, et al.,* 423 F.3d 989, 997 (9th Cir. 2005) (noting discretion vested in the EPA to consider various factors in determining whether a precursor "contributes significantly" to PM_{10} levels).

> contribute to levels which exceed the standard in the area. The intent of CAA section 189(e) in applying control requirements to PM$_{2.5}$ precursors is to ensure expeditious attainment of the standard. However, if conditions in a particular area are such that control of sources of one or more precursors does not reduce PM$_{2.5}$ concentrations in the area, then those controls will not help the area attain (expeditiously or otherwise). Therefore, the EPA disagrees with commenters who argue that sensitivity-based contribution analyses are not appropriate for determining if precursors do not significantly contribute to PM$_{2.5}$ levels in the area. The EPA believes that sensitivity-based contribution analyses can be useful for determining whether adoption of control requirements for sources of a particular precursor would be effective in reducing PM$_{2.5}$ concentrations, and can be useful for determining whether potential emissions increases under the NNSR program would lead to insignificant air quality changes. For this reason, the final rule allows states to conduct sensitivity-based contribution analyses for the comprehensive, major stationary source, and NNSR precursor demonstrations.[24]

Based on our evaluation of the precursor demonstrations in the 2012 PM$_{2.5}$ Plan, we agree with Earthjustice's claim that ammonia emission sources "contribute significantly" to PM$_{2.5}$ levels that exceed the PM$_{2.5}$ NAAQS in the SJV and that an ammonia control evaluation is therefore necessary to satisfy the requirements of the Act for the 2006 PM$_{2.5}$ NAAQS. For the reasons provided in our proposed rule, however, we conclude that VOC emissions do not "contribute significantly" to ambient PM$_{2.5}$ levels that exceed the 2006 PM$_{2.5}$ NAAQS in the SJV area and that a VOC control evaluation therefore is not necessary in this Plan. As the commenter has not raised any specific concern regarding our proposal on VOC emissions, we are not addressing these issues further with respect to VOCs.

Comment 5: The District states that it is important to acknowledge the public health co-benefits of reducing NO$_X$ emissions in the region. The District states that ozone production in the SJV is limited by NO$_X$ concentrations relative to VOC concentrations, and that NO$_X$ reductions typically involve the elimination, reduction, and/or control of hydrocarbon combustion sources, and produce net reductions in direct particulates, metals, organic carbon, elemental carbon, and hazardous air pollutants. The District asserts that reductions in secondary ammonium nitrate are not accompanied by these additional co-benefits.

Response 5: We agree with the commenter that it is important to reduce NO$_X$ emissions for improved public health in the San Joaquin Valley, because it is a precursor to both PM$_{2.5}$ and ozone. As to the air quality benefits of reductions in secondary ammonium nitrate, theoretically these air quality benefits could be achieved by reductions in either NO$_X$ emissions or ammonia emissions. Reductions in secondary ammonium nitrate through NO$_X$ control would achieve the co-benefits identified by the commenter. Given that there is no atmospheric chemistry connection between ammonia emissions and ozone production, we agree with the commenter that ammonia reductions would not achieve the same co-benefits with respect to ozone that NO$_X$ reductions achieve. Ammonia reductions may, however, achieve other air quality co-benefits depending on the specifics of the ammonia controls, which are not explored in the Plan but may be uncovered by additional analysis. In any case, this issue does not affect our conclusion that ammonia is a PM$_{2.5}$ precursor subject to control evaluation for purposes of the 2006 PM$_{2.5}$ NAAQS in the SJV.

C. Comments Regarding RACM/RACT and Adopted Control Strategy

Comment 6: Earthjustice argues that the EPA should disapprove the Plan's RACM/RACT demonstration because it does not include all reasonably available control measures. Earthjustice asserts that the EPA's review of this demonstration in its proposed rule "does little more than rubberstamp the District's unsupported assertions" that all reasonable controls have been exhausted, and identifies six source categories for which it claims that existing control measures could reasonably be strengthened or other reasonable new control measures have yet to be adopted and implemented.

Response 6: We disagree with these arguments. Section 107(a) of the CAA provides states with both authority and primary responsibility for developing SIPs that meet applicable statutory and regulatory requirements for attaining, maintaining, and enforcing the NAAQS. States have discretion in formulating their SIPs, and the EPA is required to approve a SIP submission that satisfies the applicable requirements of the Act.[25]

As explained in our proposed rule, the 2012 PM$_{2.5}$ Plan discusses the District's process for evaluating potential RACM/RACT in accordance with the EPA's recommendations in the General Preamble and describes each of the control measures for sources of direct PM$_{2.5}$, NO$_X$, SO$_2$, and ammonia that the Plan relies on to satisfy the RACM/RACT requirement for the 2006 PM$_{2.5}$ NAAQS.[26] For the reasons provided in our proposed rule and further below, we conclude that the 2012 PM$_{2.5}$ Plan provides for the implementation of all RACM/RACT that could reasonably be implemented in the SJV by the statutory implementation deadline, as required by CAA sections 172(c) and 189(a)(1)(C).

We note that, as of the date of our proposed action on the 2012 PM$_{2.5}$ Plan and 2014 Supplement, which published on January 13, 2015, it was not practicable for the state to adopt additional control measures for implementation by the RACM implementation deadline under CAA section 189(a)(1)(C), which was December 14, 2013.[27] The State and District must, however, include in the Serious area plan for the 2006 PM$_{2.5}$ NAAQS, which is due August 21, 2017, provisions to assure that the best available control measures (BACM) for the control of PM$_{2.5}$ and PM$_{2.5}$ precursors shall be implemented no later than 4 years after the date the area was reclassified as a Serious area, *i.e.*, by February 19, 2020.[28] The required evaluation of BACM/BACT control measures in the Serious area plan must address sources of direct PM$_{2.5}$ and all PM$_{2.5}$ precursors, except for any PM$_{2.5}$ precursor(s) for which the State submits and the EPA approves a comprehensive precursor demonstration consistent with the requirements of subpart 4 of part D, title I of the Act. In accordance with the requirements of CAA section 172(c)(6), the Serious area plan must also include any additional feasible measures to control emissions of direct PM$_{2.5}$ and PM$_{2.5}$ precursors that are necessary or appropriate to provide for attainment of the 2006 PM$_{2.5}$ NAAQS as expeditiously as practicable and no later than December 31, 2019.[29]

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[24] EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at Section III.C, p. 59.

[25] CAA section 110(k)(3), 42 U.S.C. 7410(k)(3) and 40 CFR 52.02(a); *see also Union Elec. Co.* v. *EPA*, 427 U.S. 246, 250 (1976); *Train* v. *Natural Res. Def. Council*, 421 U.S. 60, 79 (1975).

[26] 80 FR 1816, 1827–1830.

[27] The SJV area was designated nonattainment for the 2006 PM$_{2.5}$ NAAQS effective December 14, 2009. 74 FR 58688 (November 13, 2009) and 40 CFR 81.305. Therefore, the statutory deadline for implementation of RACM in the SJV under CAA section 189(a)(1)(C) for this NAAQS was December 14, 2013.

[28] The EPA reclassified the SJV area as a Serious nonattainment area for the 2006 PM$_{2.5}$ NAAQS effective February 19, 2016. 81 FR 2993 (January 20, 2016) (final reclassification) and 81 FR 42263 (June 29, 2016) (correcting amendment). Therefore, the statutory deadline for implementation of BACM in the SJV under CAA section 189(b)(1)(B) for this NAAQS is February 19, 2020.

We respond below to the specific comments pertaining to the six source categories highlighted by Earthjustice.

Comment 6a: Standards for Agricultural Equipment. Earthjustice asserts that the District's "replacement of more than 1,000 pieces of off-road equipment and agricultural equipment" through implementation of incentive programs has demonstrated the feasibility of emission controls on off-road agricultural equipment and argues that CARB has the ability to create binding, enforceable regulations to reduce NO_X emissions from off-road agricultural equipment to hasten attainment of the 2006 $PM_{2.5}$ NAAQS in the SJV.

Response 6a: To the extent Earthjustice intended to argue that the replacement of off-road agricultural equipment through incentive programs implemented in the SJV demonstrates that NO_X controls for such equipment are both technologically and economically feasible, we disagree.

Given the commenter did not specify the types and/or sizes of off-road equipment for which it believes NO_X controls are feasible, we evaluated several types of off-road agricultural equipment replacement projects funded through the Carl Moyer Memorial Air Quality Standards Attainment Program in the SJV in recent years to determine the costs and technical issues associated with such replacements. We used the SJVUAPCD's "Annual Demonstration Report" data sheets for 2013,[30] 2014,[31] and 2015,[32] which the District submitted pursuant to SJVUAPCD Rule 9610, to determine the cost effectiveness and technological feasibility of off-road agricultural equipment replacements. We limited our analysis to projects categorized as "off-road" and as "vehicle replacements," and that included data for "cost of new equip vehicle" [33] and non-zero emission reductions values reported for NO_X and/or particulate matter (PM).[34] Off-road agricultural equipment encompasses a wide variety of types of equipment. The 1807 pieces of equipment listed in the data sheets that we reviewed include: Almond shakers, almond sweepers, backhoes, bale wagons, balers, bulk carriers, combines, cotton pickers, forage harvesters, forklifts, harvesters, hay haulers, loaders, silage baggers, sprayers, swathers, tomato harvesters, tractors, tractor crawlers, and wheel loaders. Additionally, as seen in Tables 2, 3, and 4 below, the data sheets identify a wide range of equipment horsepower levels and capital costs of replacing agricultural off-road equipment, from which the EPA calculated mean and median values and cost-effectiveness values for NO_X controls.[35]

TABLE 2—HORSEPOWER FOR OFF-ROAD AGRICULTURAL EQUIPMENT

	Horsepower (HP)	Project ID	Date of "Annual Demonstration Report" data sheet identifying project
Minimum	28	C–21377–A	2014
Maximum	653	C–21973–A	2014
Mean	128		
Median	105		

Source: Minimum and maximum horsepower based on EPA review of SJVUAPCD, "Annual Demonstration Report" data sheets for 2013, 2014, and 2015. Mean and median values calculated by EPA.

TABLE 3—COST OF OFF-ROAD AGRICULTURAL EQUIPMENT

	Cost of new equipment ($)	Project ID	Date of "Annual Demonstration Report" data sheet identifying project
Minimum	10,031.50	C–22064–A	2014
Maximum	685,736.52	C–27498–A	2015
Mean	82,182.69		
Median	51,212.29		

Source: Minimum and maximum cost based on EPA review of SJVUAPCD, "Annual Demonstration Report" data sheets for 2013, 2014, and 2015. Mean and median values calculated by EPA.

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[29] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at 40 CFR 51.1010(a)(4)(ii). Although this regulatory text is not yet effective, it reflects the EPA's interpretation of the statutory requirements.

[30] Available at *http://www.valleyair.org/MOP/docs/069610ProjectDataforPublicUNLOCKED-1-30-14.xlsx.*

[31] Available at *http://www.valleyair.org/MOP/docs/9610ProjectDataforPublicUNLOCKED-8-11-14.xlsx.*

[32] Available at *http://www.valleyair.org/MOP/docs/9610ProjectDataforPublic2015.xlsx.*

[33] We did not evaluate the 125 projects in the 2014 Data Sheet categorized as "off-road" and as "vehicle replacements" for which the Data Sheet identified "cost retrofit" instead of "cost of new equip vehicle" values.

[34] We did not evaluate the 29 projects in the 2013 Data Sheet categorized as "off-road" and as "vehicle replacements" for which the Data Sheet identified zero NO_X and PM emission reductions.

[35] We calculated the cost-effectiveness of NO_X controls by dividing the "Cost of New Equipment" values by the "NO_X Lifetime Reduced (tons)" values for each of the identified projects to obtain $/ton values.

TABLE 4—COST EFFECTIVENESS OF NO_X CONTROL FOR OFF-ROAD AGRICULTURAL EQUIPMENT

	Cost effectiveness ($/ton)	Project ID	Date of "Annual Demonstration Report" data sheet identifying project
Minimum	1,141.00	C–8160A	2013
Maximum	436,140.00	C–22654–A	2014
Mean	38,687.61		
Median	18,863.95		

Source: EPA, "Agricultural Mobile Engine Projects—EPA cost-effectiveness calculations," July 21, 2016.

The significant costs associated with replacing off-road agricultural equipment in the SJV indicate that replacement of such equipment without funding assistance generally is not economically feasible at this time. In addition, the wide variations in the sizes and uses of such equipment in the SJV and the available control technologies indicate that replacement of off-road agricultural equipment in the SJV may not be technically feasible for many types of equipment. Accordingly, we disagree with Earthjustice's suggestion that requirements to replace off-road agricultural equipment are required RACM in the SJV.

Comment 6b: Fleet Rules. Earthjustice comments that the District can further reduce emissions from mobile sources by adopting additional "fleet" rules to regulate emissions from publicly-owned vehicles. Earthjustice notes that while the District currently maintains a fleet rule only for school buses, the South Coast Air Quality Management District (SCAQMD) has adopted rules for buses; light-, medium-, and heavy-duty public fleet vehicles; waste collection vehicles; airport ground transportation such as taxis and shuttles; and street sweepers. Earthjustice states that the District should implement similar restrictions on publicly-owned vehicles.

Response 6b: We disagree with Earthjustice's suggestion that adoption of additional "fleet" rules is necessary to satisfy the RACM/RACT requirement for the 2006 $PM_{2.5}$ NAAQS in the SJV.

As the commenter notes, the SCAQMD has adopted several rules to encourage public agencies and some private entities to shift to the use of lower emissions vehicles,[36] including the following:

Rule 1186.1 Less-Polluting Street Sweepers, adopted August 18, 2000;
Rule 1191 Clean On-Road Light and Medium Duty Public Fleet Vehicles, adopted June 16, 2000;
Rule 1192 Clean On-Road Transit Buses, adopted June 16, 2000;
Rule 1193 Clean On-Road Residential and Commercial Refuse Collection Vehicles, adopted June 16, 2000.
Rule 1194 Commercial Airport Ground Access Vehicles, adopted August 18, 2000;
Rule 1195 Clean On-Road School Buses, adopted April 20, 2001; and
Rule 1196 Clean On-Road Heavy-Duty Public Fleet Vehicles, adopted October 20, 2000.

As explained in Appendix C of the 2012 $PM_{2.5}$ Plan, both CARB and the SJVUAPCD have adopted fleet rules to reduce emissions from specific types of on-road vehicle fleets, *e.g.*, CARB's Fleet Rule for Public Agencies and Utilities, which addresses diesel particulate matter from vehicle fleets operated by public agencies and utilities, and SJVUAPCD Rule 9310 (School Bus Fleets), which requires replacement, retrofit, or repowering of older diesel-fueled school buses.[37] The District acknowledges in Appendix C of the Plan that the SCAQMD is implementing a fleet rule that requires solid waste collection vehicle fleets to operate entirely on alternative fuel beginning in 2011 but explains that transitioning a fleet from diesel to alternative fuel can be costly and may not be economically feasible in the SJV.[38] Additionally, according to the SJVUAPCD, the emissions benefit associated with such a transition is minimal given the stringent particulate matter requirements under CARB's Fleet Rule for Public Agencies, and the relatively small difference in NO_X emissions, if any, between diesel and alternative fuel vehicles.[39] The commenter provides no information to support a claim that the SJVUAPCD could reasonably have adopted and implemented identical or similar rules in the SJV prior to the RACM/RACT implementation deadline, which was December 14, 2013. We note that none of the SCAQMD fleet rules identified above has been submitted for approved into the California SIP.

Comment 6c: Indirect Source Review (ISR) Improvements. Earthjustice comments that the District can obtain additional emissions reductions by expanding the applicability of its ISR rule, which Earthjustice notes was last updated in 2005. Earthjustice suggests that the District could eliminate provisions that allow businesses to mitigate their emissions by paying fees (or establish a minimum emission level for when a business may use this option), add limits for $PM_{2.5}$ emissions, and require projects to achieve greater emissions reductions.

Response 6c: We disagree with the commenter's suggestion that revisions to SJVUAPCD Rule 9510 ("Indirect Source Review") are necessary to satisfy RACM requirements for the 2006 $PM_{2.5}$ NAAQS in the SJV.

SJVUAPCD Rule 9510, as adopted December 15, 2005, requires applicants for development projects of certain sizes and certain transportation or transit projects to reduce NO_X and particulate matter (PM) emissions from the development and use of such projects through various on-site mitigation measures or payment of fees to fund off-site emission reduction projects. The EPA approved SJVUAPCD Rule 9510 into the California SIP at 76 FR 26609 (May 9, 2011) but explained in that action that the EPA and the District were acting under section 110(a)(5) of the CAA. Under that section, the EPA is prohibited from requiring states to include ISR programs in SIPs. Specifically, CAA section 110(a)(5)(A)(i) states that any State *may* include in a State implementation plan, but the Administrator *may not require* as a condition of approval of such plan under this section, any indirect source review program. Section 110(a)(5)(A)(i) also states that the Administrator may approve and enforce, as part of an applicable implementation plan, an indirect source review program which the State chooses to adopt and submit as part of its plan.[40] Because SJVUAPCD Rule 9510 constitutes an ISR program, the EPA may not require the District to consider revisions to this rule, for RACM purposes or otherwise.

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[36] The applicability of these rules was narrowed to exclude federal fleets and certain private fleets. *See http://www.aqmd.gov/docs/default-source/Regulations/Fleet-Rules/fleetruleadvisory-july202005.pdf?sfvrsn=0.*

[37] 2012 $PM_{2.5}$ Plan, Appendix C at C–7 to C–11.

[38] *Id.* at C–8, C–9 (noting that "establishing new alternative fuel infrastructure can cost millions of dollars and alternative fuel SWCVs generally cost $25,000 more than diesel").

[39] *Id.*

Comment 6d: Fireplace Rule Improvements. Earthjustice comments that the District could reduce direct PM$_{2.5}$ emissions by making SJVUAPCD Rule 4901 (Wood Burning Fireplaces and Wood Burning Heaters) more stringent. Earthjustice notes that this rule was updated in 2014, but argues that this update did not make the rule "as stringent as it reasonably could," because it allows cleaner classes of wood-burning heaters to be used at ambient concentrations up to 65 microgram per meter cubed (μg/m^3). Earthjustice argues that a more appropriate threshold would be 35 μg/m^3, the attainment level for the 2006 PM$_{2.5}$ NAAQS, and that the District should amend the rule to disallow use of these heaters when concentrations are expected to exceed this level. Earthjustice asserts that the District "should prioritize making the rule as protective as possible" to reduce direct PM$_{2.5}$ emissions.

Response 6d: We disagree with the commenter's suggestion that revisions to SJVUAPCD Rule 4901 are necessary to satisfy RACM requirements for the 2006 PM$_{2.5}$ NAAQS in the SJV.

Consistent with the District's rule amendment commitments in the 2012 PM$_{2.5}$ Plan,[41] the SJVUAPCD amended Rule 4901 on September 18, 2014, and CARB submitted the amended rule to the EPA for SIP action on November 6, 2014.[42] On August 15, 2016, Acting Regional Administrator Alexis Strauss signed a notice of final rulemaking to approve SJVUAPCD Rule 4901, as amended September 18, 2014, as meeting applicable CAA requirements and implementing RACM/RACT for PM$_{2.5}$ emissions from wood burning devices.[43]

Comment 6e: Interim Charbroiling Regulations. Earthjustice argues that the District has delayed updating its charbroiler rule even though the Bay Area Air Quality Management District (BAAQMD) has already implemented regulations on under-fired charbroilers. Earthjustice points out that in 2012, it and other organizations asked the District to update the rule sooner, to include controls similar to those in the Bay Area and to follow up with another rule update when new technologies are reasonably available.

Response 6e: We disagree with the commenter's suggestion that SJVUAPCD Rule 4692 (Commercial Charbroiling) fails to satisfy RACM requirements for the 2006 PM$_{2.5}$ NAAQS in the SJV and that control measures for under-fired charbroilers are necessary to satisfy these requirements.

SJVUAPCD Rule 4692, as amended September 17, 2009, applies to chain-driven charbroilers used in commercial meat cooking and requires a catalytic oxidizer or alternative controls with a control efficiency of at least 83 percent for PM$_{10}$ emissions and 86 percent for VOC emissions. The rule exempts charbroilers used to cook less than 400 pounds of meat in a calendar week, and other limited-use charbroilers that do not exceed weekly and rolling 12-month maximum use limits and that have not previously been required to comply with the rule's control requirements. It does not regulate under-fired charbroilers.[44]

The BAAQMD is the only air district that we are aware of that has adopted regulations to reduce emissions from under-fired charbroilers. BAAQMD Regulation 6, Rule 2 (Commercial Cooking Equipment),[45] applies to chain-driven charbroilers in restaurants that purchase 500 pounds or more of beef per week, and to under-fired charbroilers in restaurants that purchase 1,000 pounds or more of beef per week. The rule requires these restaurants to control emissions using a certified control device and to register charbroilers and associated emission control devices with the BAAQMD. The rule exempts low-utilized charbroilers, including under-fired charbroilers used to grill less than 800 pounds of beef per week.[46]

According to BAAQMD planning and compliance staff, the control requirements in Regulation 6, Rule 2 for under-fired charbroilers have not yet been implemented in practice.[47] BAAQMD staff noted that no under-fired charbroilers in the Bay Area are currently registered pursuant to Regulation 6 Rule 2, indicating that restaurants in the Bay Area are operating below the thresholds that trigger the requirements. In addition, the BAAQMD's most recent inspections found that restaurants were below these thresholds.[48] Significantly, the BAAQMD has not yet certified any emission control devices for under-fired charbroilers. BAAQMD staff explained that they are waiting to receive and review final test reports from the University of California at Riverside, Center for Environmental Research and Technology (CE–CERT) before making certifications.[49]

The SJVUAPCD's 2012 PM$_{2.5}$ Plan summarizes PM control technology for under-fired charbroilers.[50] It finds that catalytic oxidizers are not effective for under-fired charbroilers because the exhaust from these devices loses too much heat before it reaches the catalyst. The Plan lists High Efficiency Particulate-Arresting (HEPA) filtration, Electrostatic Precipitators (ESP), and Wet Scrubbers as potentially more effective control technology for under-fired charbroilers, but notes that the SJVUAPCD found these technologies were "unproven and extremely costly" when it amended SJVUAPCD Rule 4692 in 2009. During that amendment process, the District found that the initial costs for these controls ranged from $37,500 to $104,000, which results in a cost of approximately $58,200 per ton of PM$_{2.5}$ reduced. The District has estimated the total costs of installing, operating, and maintaining these controls to be as much as 20 to 30 percent of a restaurant's net profits.[51] As a result, the District decided not to adopt regulations for under-fired charbroilers as part of its rule amendments in 2009. We note that the Plan contains the District Governing Board's commitment to adopt control measures for under-fired charbroilers in 2016.[52]

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[40] CAA section 110(a)(5)(A)(i).

[41] 80 FR 1816, 1832 at Table 3 (January 13, 2015); *see also* 2012 PM$_{2.5}$ Plan, Chapter 5 ("Control Strategy"), Section 5.3 ("New Control Measures"), p. 5–21 to 5–22.

[42] 80 FR 58637 (September 30, 2015).

[43] EPA, Final Rule, "Approval of California Air Plan Revisions, San Joaquin Valley Unified Air Pollution Control District," August 15, 2016 (pre-publication notice).

[44] SJVUAPCD Rule 4692 (amended September 17, 2009), sections 4.1, 5.1, and 5.2.

[45] BAAQMD Regulation 6, Rule 2 (adopted December 5, 2007), available at *http://www.arb.ca.gov/DRDB/BA/CURHTML/R6-2.PDF.*

[46] BAAQMD Regulation 6, Rule 2 (adopted December 5, 2007), sections 6–2–102, 6–2–110, 6–2–111, 6–2–300, and 6–2–400.

[47] Email dated April 4, 2016, from Virginia Lau of the BAAQMD to Stanley Tong of EPA Region 9, regarding "Update on Bay Area charbroiler registration."

[48] BAAQMD staff noted that these inspections occurred during a period of economic recession, and that conditions may have changed since. Email dated April 4, 2016, from Virginia Lau of the BAAQMD to Stanley Tong of EPA Region 9, regarding "Update on Bay Area charbroiler registration."

[49] CE–CERT informed SCAQMD that charbroiler testing will be delayed for up to four months due to fire suppression system upgrades in its test kitchen. Email dated March 16, 2016 from Michael Laybourn of the SCAQMD to Stanley Tong of EPA Region 9, regarding "Charbroiler Testing."

[50] 2012 PM$_{2.5}$ Plan, Appendix D at D–111 to D–117.

[51] Action Summary Minutes, San Joaquin Unified Air Pollution Control District, Governing Board, August 20, 2009, page 7, available at *http://www.valleyair.org/Board_meetings/GB/agenda_minutes/Minutes/2009/Minutes_GB_2009_Aug.pdf.*

A study conducted by the University of California at Berkeley [53] arrives at a similar conclusion regarding the cost of PM controls for under-fired charbroilers. Using 2007 economic census data, the study estimates the average annual profit of restaurants in the SJVUAPCD area to be $23,000–$47,000 per establishment, for a profit margin of 3.5–5.9 percent. Similarly, the study estimates the annual profit for average large restaurants (*i.e.*, restaurants averaging 60 employees) to be approximately $110,000. The study also finds that the average capital cost for particulate matter (PM) emission controls such as an ESP, HEPA filtration, or wet scrubber can range from approximately $38,750 to $50,000, with average annualized costs for installation and operation of $11,000–$15,000. The study calculates the total costs associated with these controls to be approximately 10–14 percent of an average large restaurant's profits. The study states that "[t]hese figures may appear modest . . . given that installing control technologies would amount to only a tenth of [large] restaurant profits. However . . . this figure is several times larger than the case of successful chain-driven charbroiler regulations, where the cost of installing catalytic oxidizers represented just 2.2 percent of average restaurant profits." [54] The study notes that its annualized cost estimates parallel SJVUAPCD's estimates, even though the data were drawn from different sources.[55]

We anticipate the CE–CERT research report will help clarify the cost effectiveness of various under-fired charbroiler emission control technologies, some of which are prototypes, which will supplement the earlier Berkeley study to help inform more effective rule development.[56] Additionally, the District is currently undertaking efforts that may yield additional information relevant to whether additional controls for charbroilers would be appropriate and feasible in the SJV. To help study the technological feasibility and effectiveness of potential control technologies, the SJVUAPCD Governing Board approved $750,000 for its Restaurant Charbroiler Technology Partnership program to fund PM control technology demonstration projects for under-fired charbroilers at Valley restaurants.[57] The District's funding would include the full purchase cost, installation, operation, maintenance, and other costs such as modifications to existing system configurations and structural reinforcements, and will help evaluate control systems operations, maintenance, and labor costs in the field. Completion of these research efforts will allow regulatory agencies to evaluate overall PM reduction strategies, which will help in designing economically and technically feasible regulations that can achieve the necessary PM reductions.

Based on these evaluations, we find that SJVUAPCD Rule 4692 implements RACM/RACT for charbroilers for purposes of the 2006 PM$_{2.5}$ NAAQS in the SJV.

Comment 6f: Performance Standards for Flares. Earthjustice comments that the District could strengthen Rule 4311 (Flares) by adopting a performance-based standard for flaring. Earthjustice states that the District should assess the strength of its rule against rules in other areas with high oil and gas production, and suggests North Dakota as an example. As explained by Earthjustice, North Dakota requires operators to meet targets for natural gas capture that increase over time from 74 percent in 2014 to an expected 90 percent by 2020, and allows state regulators to restrict oil production if the operators do not meet these targets. Earthjustice says that the District could "borrow from" this approach by assessing the percentage of natural gas flared in the San Joaquin Valley and developing regulations to reduce flaring.

Response 6f: We disagree with the commenter's suggestion that revisions to SJVUAPCD Rule 4311 (Flares) are necessary to satisfy RACM requirements for the 2006 PM$_{2.5}$ NAAQS in the SJV.

SJVUAPCD Rule 4311, as amended June 18, 2009, limits VOC, NO$_X$, and sulfur oxides (SO$_X$) emissions from industrial operations involving the use of flares. The rule includes general requirements for combusting waste gases, emission standards for ground-level enclosed flares, and performance targets for petroleum refinery flares. Operators of refinery flares and flares with capacity greater than 5.0 MMBtu/hour are required to submit flare minimization plans (FMPs) containing information such as detailed process diagrams, descriptions of upstream equipment, and evaluations of preventive measures to reduce flaring.[58] The rule prohibits flaring unless it is done consistently with a District-approved FMP.[59] Additionally, the rule includes monitoring, recordkeeping, and reporting requirements, including a requirement for operators to investigate and report flaring events.[60]

As the commenter notes, North Dakota has adopted rules governing flaring in the oil and gas industry, through provisions of the North Dakota Century Code and an Order issued by the Industrial Commission of North Dakota. Section 38–08–06.4 of the North Dakota Century Code allows oil wells to flare gas during the first year of production, and thereafter requires wells either to be capped or to be equipped with approved capture or control measures that, at a minimum, reduce flared gas by at least 60 percent, unless the operator can demonstrate that such measures are not economically feasible.[61] Industrial Commission Order 24665 adopts tiered gas capture goals that include a target of 74 percent capture in 2014 and an end target of 90 percent capture in 2020.[62]

The SJVUAPCD's 2012 PM$_{2.5}$ Plan states that Rule 4311 is more stringent than flare rules in other California air districts. Appendix D of the Plan compares Rule 4311 to SCAQMD Rule 1118, BAAQMD Rules 12–11 and 12–12, and Santa Barbara County Air Pollution Control District (SBCAPCD) Rule 359.[63] According to the District, these rules contain requirements for FMPs and monitoring, recordkeeping, and reporting provisions similar to those in SJVUAPCD Rule 4311, and emission standards for ground-level enclosed flares, but Rule 4311 applies to a wider range of operations and does not include certain exemptions present in the other districts' rules.[64] The District also states that the Sacramento Metropolitan Air Quality Management District (SMAQMD) and Ventura County Air Pollution Control District (VCAPCD) do not have specific prohibitory rules for flares.[65]

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[52] 2012 PM$_{2.5}$ Plan, Chapter 5 ("Control Strategy"), Section 5.3 ("New Control Measures"), p. 5–21 to 5–22, and SJVUAPCD Governing Board Resolution 2012–12–19 (December 20, 2012), page 4; *see also* 80 FR 1816, 1832 at Table 3 (January 13, 2015).

[53] Bellisario, J., Mandel, B., Perkins, J., Ruan, Y., "Regulating Emissions from Under-fired Charbroilers," University of California, Berkeley, Goldman School of Public Policy, May 2012.

[54] *Id.* at p. 24.

[55] *Id.* at p. 24.

[56] The SCAQMD, BAAQMD, SJVUAPCD, and EPA Region 9 are part of a workgroup to provide input on the CE–CERT under-fired charbroiler testing research.

[57] *See* Restaurant Charbroiler Technology Partnership, available at *http://valleyair.org/grants/rctp.htm*, and "Charbroilers Come Under San Joaquin Valley Air District's Microscope," The Modesto Bee, December 27, 2015, *http://www.recordnet.com/article/20160101/NEWS/160109993*.

[58] SJVUAPCD Rule 4311 (adopted June 18, 2009), sections 5.8 and 6.5.

[59] *Id.*

[60] *Id.* at sections 6.1 and 6.2.

[61] North Dakota Century Code, Section 38–08–06.4, as effective January 2016.

[62] State of North Dakota, Industrial Commission Order No. 24665 (dated July 1, 2014).

[63] The 2012 PM$_{2.5}$ Plan mistakenly identifies the Santa Barbara rule as "Rule 4359." 2012 PM$_{2.5}$ Plan, Appendix D at D–71.

[64] 2012 PM$_{2.5}$ Plan, Appendix D at D–71.

The District has addressed the North Dakota Century Code and the Industrial Commission Order in Appendix C of the "2015 Plan for the 1997 $PM_{2.5}$ Standard" (hereafter "2015 $PM_{2.5}$ Plan").[66] There, the District concludes that SJVUAPCD Rule 4311 is more stringent than the North Dakota rule. Among its findings in support of this conclusion, the District notes that Rule 4311 applies to a broader range of sources and achieves a higher percentage of gas capture.[67] Appendix C of the 2015 $PM_{2.5}$ Plan also discusses SBCAPCD Rule 359, which includes a performance standard for gas volume.[68] The District concludes that Rule 4311 is more stringent than this rule, citing reasons that include Rule 4311's applicability to a broader range of sources, fewer exemptions, and greater percentage gas capture.[69]

We agree with the District's analysis and conclusion that SJVUAPCD Rule 4311 is at least as stringent as the rules adopted by the other California air districts and the requirements in place in North Dakota. Therefore, we disagree with the commenter's assertion that a performance-based standard like North Dakota's would be more protective than Rule 4311. While Rule 4311 does not set performance targets for reducing flared gas, information in the record indicates that it achieves emission reductions greater than those targets. Table C–11 of the 2015 $PM_{2.5}$ Plan shows that the percentage of gas flared in the SJV in the years between 2009 and 2013 has never exceeded 5 percent.[70] This analysis addresses the commenter's suggestion that the District should assess the percentage of natural gas flared in the District, and it indicates that adoption of requirements like North Dakota's would not reduce emissions from flaring in the SJV.

Based on this assessment, we find that SJVUAPCD Rule 4311 represents RACT for flaring operations in the SJV, and that the alternatives suggested by the commenter would not achieve additional emission reductions.

Comment 7: Earthjustice comments that the RACM/RACT analysis in the Plan does not include reasonable controls for condensable emissions, and that the EPA must therefore disapprove the RACM/RACT demonstration. Earthjustice states that 40 CFR 51.1002(c) requires agencies to set controls for condensable emissions beginning January 1, 2011, and quotes the EPA's prior statement at 72 FR 20586, 20652 that "[w]e expect States to address the control of direct $PM_{2.5}$ emissions, including condensables [sic] [71] with any new actions taken after January 1, 2011."

Response 7: We agree with Earthjustice's statement that the transition period under 40 CFR 51.1002(c) (as effective May 29, 2007) [72] allowing state and local agencies to submit plans that do not address condensable emissions ended on January 1, 2011. We disagree, however, with the claim that the EPA must disapprove the RACM/RACT demonstration in the Plan for failure to assess controls on condensable $PM_{2.5}$ emissions.

EPA regulations at 40 CFR 51.1002(c), as effective May 29, 2007, provide that, after January 1, 2011, for purposes of establishing emissions limits to satisfy requirements for RFP and reasonably available control measures/reasonably available control technology (RACM/RACT), states must establish such limits taking into consideration the condensable fraction of direct $PM_{2.5}$ emissions. Because direct $PM_{2.5}$ is comprised of both filterable $PM_{2.5}$ and condensable $PM_{2.5}$,[73] the EPA has explained that both the emissions inventories underlying a $PM_{2.5}$ attainment plan and any emission limits for sources of direct $PM_{2.5}$ in the control strategy must take into consideration the condensable fraction of $PM_{2.5}$ emissions.[74] As the EPA stated in the July 29, 2016 final rule to implement the $PM_{2.5}$ NAAQS, it is particularly important to ensure that both the filterable and condensable components of direct $PM_{2.5}$ emissions are accurately represented in the base year emissions inventory underlying a RACM/RACT control analysis.[75]

Chapter 4 of the 2012 $PM_{2.5}$ Plan contains a brief discussion of the District's approach to condensable $PM_{2.5}$ emissions and states that condensable particulates are included in the District's total emissions inventory for direct $PM_{2.5}$.[76] The base year inventory for direct $PM_{2.5}$ emissions is provided in Appendix B of the 2012 $PM_{2.5}$ Plan and includes condensable emissions. Specifically, the $PM_{2.5}$ emissions inventory for commercial cooking operations incorporates emission factors from a source testing study that collected both filterable and condensable particulate matter (PM).[77]

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[65] *Id.* The VCAPCD does not have a specific flaring rule, but VACPCD Rule 54, "Sulfur Compounds" includes requirements for flaring events, including FMPs. The District's "2015 Plan for the 1997 $PM_{2.5}$ Standard" ("2015 $PM_{2.5}$ Plan") includes this rule in a table comparing Rule 4311 to other California air district rules, and states that SJVUAPCD Rule 4311 is at least as stringent. 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at page C–79.

[66] 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at page C–81.

[67] In its comparison of Rule 4311 to the North Dakota provisions, the 2015 $PM_{2.5}$ Plan states that Rule 4311 "requires 95% capture and treatment of produced gas." 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at page C–82. We interpret this to mean that the rule achieves at least 95 percent capture in practice, as demonstrated at Table C–11 of the Plan. 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at page C–80. *See* email dated May 20, 2016, from Sheraz Gill of the SJVUAPCD to Andrew Steckel of EPA Region 9, regarding Small flares question.

[68] 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at pp. C–79 to C–81.

[69] *Id.* at C–81.

[70] 2015 $PM_{2.5}$ Plan, Appendix C: BACM and MSM for Stationary and Area Sources, at page C–79. SJVUAPCD staff confirmed that the data in this table comes from the annual emissions inventory reports submitted by sources to the District. Email dated April 27, 2016, from Sheraz Gill of the SJVUAPCD to Andrew Steckel of EPA Region 9, regarding SJV flares data inquiry.

[71] The **Federal Register** notice uses the term "condensable PM."

[72] 72 FR 20586 (April 25, 2007). The EPA's recent final rule to implement the $PM_{2.5}$ NAAQS also requires that emission limitations for $PM_{2.5}$ sources address condensable $PM_{2.5}$. *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at p. 567 (requiring at 40 CFR 51.1009(c) that, for new or revised source emissions limitations on sources of direct $PM_{2.5}$ emissions, states apply such emissions limitations either to the total of the filterable plus condensable fractions of direct $PM_{2.5}$, or to filterable $PM_{2.5}$ and condensable $PM_{2.5}$ separately).

[73] Certain commercial or industrial activities involving high temperature processes (*e.g.*, fuel combustion, metal processing, and cooking operations) emit gaseous pollutants into the ambient air which rapidly condense into particle form. These "condensable" particulate matter emissions exist almost entirely in the 2.5 or less micron range and can consist of organic material, sulfuric acid and metals. 80 FR 15340, 15343 at n. 7 (March 23, 2015); *see also* 72 FR 20586, 20651 (April 25, 2007).

[74] *See, e.g.*, 80 FR 15340, 15412 (March 23, 2015) (discussing requirement to address condensable $PM_{2.5}$ in base year emissions inventory and related SIP control strategies).

[75] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at pp. 66–77, 90–104 and 139–140 (discussing requirements to include condensable $PM_{2.5}$ in base year emissions inventories and in RACM/RACT control evaluations); *see also* 80 FR 15340 at 15378, 15412.

[76] *See* 2012 $PM_{2.5}$ Plan at p. 4–22.

[77] *See* "2006 Area Source Emissions Inventory Methodology 690—Commercial Cooking Operations," available at *http://www.valleyair.org/Air_Quality_Plans/EmissionsMethods/MethodForms/Current/CommercialCooking2006.pdf*. *See also* Welch, W.A. and Norbeck, J.M., 1998, "Development of Emission Test Methods and Emission Factors for Various Commercial Cooking Operations," TO–98–14–3 and email dated May 20, 2016, from W. Welch of the SCAQMD to Stanley Tong of USEPA, RE:

Similarly, the SJVUAPCD's $PM_{2.5}$ emission factors for natural gas fired boilers, turbines and engines in the manufacturing and industrial category are based on the EPA's AP–42 emission factors, which include both filterable and condensable PM.[78] Also, PM in the emissions inventory from biomass boilers and natural gas turbines for the electric utilities sector is based on PM_{10} testing required by operating permits and includes both filterable and condensable PM.[79] According to the emissions inventories in the 2012 $PM_{2.5}$ Plan, approximately 38 percent of the 2007 direct $PM_{2.5}$ inventory for stationary and area sources comes from fugitive dust and farming, emission sources that generally do not produce condensable PM emissions. Stationary source combustion processes that emit condensable PM, such as electric utilities, commercial cooking operations and glass melting furnaces, account for approximately 13.5 percent of the 2007 $PM_{2.5}$ inventory for stationary and area sources. Residential fuel combustion, fires, and managed burning activities account for 44 percent of the stationary and area source inventory, and miscellaneous industrial processes make up the remainder of the non-mobile source inventory.[80]

The 2012 $PM_{2.5}$ Plan relies on several SJVUAPCD rules regulating direct PM emissions as part of the $PM_{2.5}$ control strategy, including Rule 4692 (Commercial Charbroiling, amended September 17, 2009), Rule 4103 (Open Burning, amended April 15, 2010), Rule 4354 (Glass Melting Furnaces, amended May 19, 2011), and Rule 4901 (Wood Burning Fireplaces and Wood Burning Heaters, amended September 18, 2014).[81] Of the SJVUAPCD rules that control direct PM emissions, only two establish emission limits for PM: Rule 4692 and Rule 4354. Both of these rules contain control requirements that apply to condensable PM and require sources to use test methods that measure condensable PM.

Specifically, section 5.2 of SJVUAPCD Rule 4692 requires that each chain-driven charbroiler be equipped and operated with a catalytic oxidizer that has a control efficiency of at least 83 percent for PM_{10} emissions, and section 6.5.1 of the rule requires testing in accordance with the "South Coast Air Quality Management District's Protocol," which requires measurement of both condensable and filterable PM in accordance with SCAQMD Test Method 5.1.[82] SJVUAPCD Rule 4692 defines PM_{10} as defined in SJVUAPCD Rule 1020 and states that "[f]or purposes of determining control efficiency, all particulate collected using the test method specified in Section 6.5 shall be considered PM_{10}." [83] Because section 6.5 of SJVUAPCD Rule 4692 requires measurement of both condensable and filterable PM, both condensable and filterable PM are considered PM_{10} under the rule.[84] Similarly, section 5.4 of SJVUAPCD Rule 4354 establishes emission limits for PM_{10}, also defined as in SJVUAPCD Rule 1020,[85] and states that "total PM_{10} includes both filterable PM_{10} and condensable PM_{10}." Section 6.5.9 of SJVUAPCD Rule 4354 requires testing for condensable PM emissions using EPA Method 202.[86] No other SIP control measure in the RACM/RACT demonstrations in the 2012 $PM_{2.5}$ Plan establishes direct PM emission limitations.

We therefore find that the 2012 $PM_{2.5}$ Plan adequately addresses the condensable fraction of direct $PM_{2.5}$ both in the base year emissions inventory and in the SIP control strategy.

Comment 8: Earthjustice argues that the EPA must disapprove the ammonia RACM/RACT demonstration because the District has not demonstrated that it has adopted all reasonably available control measures. According to Earthjustice, the Plan "includes no analysis of how Rules 4565, 4566, and 4570 actually control ammonia emissions," and the District's ammonia RACM/RACT demonstration "is little more than the District's rationalizations for *not* adopting reasonable controls" (emphasis in comment). Earthjustice says that the EPA has proposed to excuse the Plan's failure to analyze ammonia controls "because it was submitted too soon after the decision in *NRDC* for the District to have incorporated a full analysis of ammonia controls into the Plan." Earthjustice asserts that this consideration "provides no basis for finding that the statutory requirements have been met."

Response 8: We disagree with Earthjustice's assertion that the EPA must disapprove the ammonia RACM/RACT demonstration in the Plan. As we explained in our proposed rule, the 2014 Supplement contains a discussion of three SIP-approved District rules that regulate VOCs but also have the effect of reducing ammonia emissions in the SJV, as well as ammonia control measures implemented elsewhere that the District evaluated for technical and economic feasibility.[87] These analyses, which the EPA has developed further below, demonstrate that SJVUAPCD Rule 4565, Rule 4566, and Rule 4570 reduce ammonia emissions from confined animal facilities (CAFs) and composting operations in the SJV, which together account for

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Development of PM Charbroiling Emission Factors using SC 5.1 (confirming that tests were performed using SCAQMD Method 5.1 which includes both filterable and condensable PM).

[78] SJVUAPCD. "2006 Area Source Emissions Inventory Methodology 050—Industrial Natural Gas Combustion" at p. 3 (identifying emission factors are based on the EPA's AP–42 chapters 1.4 and 3.2, which include filterable and condensable PM).

[79] Email dated May 18, 2016, from Chay Thao of the SJVUAPCD to Stanley Tong of EPA Region 9, regarding "Gas Turbine PM source testing condensible"; *see also* SJVUAPCD, Notice of Final Action, Minor Title V Permit Modification, District Facility #C–14 (April 26, 2012), permit condition 21, available at *https://yosemite.epa.gov/R9/air/EPSS.NSF/0201370ee436adf08825653000726dc1/e76e9625e609621088257a0e00535d9c/$FILE/Public%20Notice%20Pkg.pdf* and SJVUAPCD, Notice of Final Action, Revised Final Determination of Compliance, Project Number: N–1113502 (January 18, 2012), permit condition 51, available at *https://yosemite.epa.gov/R9/air/EPSS.NSF/0201370ee436adf08825653000726dc1/5f867ce070483067882579c300793cbe/$FILE/Public%20Notice%20Package.pdf*.

[80] 2012 $PM_{2.5}$ Plan, Appendix B at B–3.

[81] 81 FR 6936 at 6951–52, Table 3 (February 9, 2016).

[82] *See* SCAQMD Protocol, *Determination of Particulate and Volatile Organic Compound Emissions From Restaurant Operations,* November 14, 1997, available at *http://yosemite.epa.gov/R9/R9Testmethod.nsf/0/3D4DEB4D21AB4AAF882570AD005DFF69/$file/SC%20Rest%20emiss.pdf* and SCAQMD Test Method 5.1, *Determination of Particulate Matter Emissions From Stationary Sources Using a Wet Impingement Train,* March 1989, available at *http://www.aqmd.gov/docs/default-source/laboratory-procedures/methods-procedures/stm-005-1.pdf?sfvrsn=2*.

[83] SJVUAPCD Rule 4692 (amended September 17, 2009), section 3.6, defining PM_{10} "as defined in Rule 1020 (Definitions)." SJVUAPCD Rule 1020 defines "particulate matter" as "any material except uncombined water, which exists in a finely divided form as a liquid or solid at standard conditions," and defines "PM–10" as "particulate matter with an aerodynamic diameter smaller than or equal to a nominal ten (10) microns as measured by the applicable state and federal reference test methods." SJVUAPCD Rule 1020 (amended February 21, 2013), sections 3.32 and 3.36, approved at 79 FR 59433 (October 2, 2014).

[84] Welch, W.A. and Norbeck, J.M., 1998, "Development of Emission Test Methods and Emission Factors for Various Commercial Cooking Operations," TO–98–14–3 (indicating that the majority of PM emitted from commercial cooking operations is less than 2.5 microns).

[85] *See* SJVUAPCD Rule 4354 (amended May 19, 2011), section 3.30, defining PM_{10} "as defined in Rule 1020 (Definitions)." SJVUAPCD Rule 1020 defines "particulate matter" as "any material except uncombined water, which exists in a finely divided form as a liquid or solid at standard conditions," and defines "PM_{10}" as "particulate matter with an aerodynamic diameter smaller than or equal to a nominal ten (10) microns as measured by the applicable state and federal reference test methods." SJVUAPCD Rule 1020 (amended February 21, 2013), sections 3.32 and 3.36, approved at 79 FR 59433 (October 2, 2014).

[86] 75 FR 80118 (December 21, 2010).

[87] 80 FR 1816 at 1827–1830 (referencing 2014 Supplement at Attachment A).

approximately 76 percent of the District's estimates of total 2015 ammonia emissions in the SJV.[88] We find these evaluations sufficient to demonstrate that the District has adopted RACM/RACT for ammonia emissions for purposes of the 2006 $PM_{2.5}$ NAAQS in the SJV.

SJVUAPCD Rule 4565 (Biosolids, Animal Manure, and Poultry Litter Operations), as adopted March 15, 2007, requires that each operator of a composting/co-composting facility with a throughput of at least 100,000 wet tons per year conduct all active or curing composting either in aerated static pile(s) vented to an emission control device with a VOC control efficiency of at least 80 percent by weight, or in an in-vessel composting system vented to an emission control device with a VOC control efficiency of at least 80 percent by weight.[89] Alternatively, the operator may implement an "alternative Class Two mitigation measure" that is determined by the SJVUAPCD Air Pollution Control Officer (APCO) and the EPA to achieve equivalent VOC emission reductions.[90] According to the District's staff report for SJVUAPCD Rule 4565, the most commonly used VOC emission control devices at composting facilities are biofilters, which are used at over twenty composting facilities in the U.S. and at least five composting facilities in California.[91] Biofilters reduce both VOC and ammonia emissions by oxidizing VOC to carbon dioxide and water and degrading ammonia emissions into nitrate.[92] For operators that use a biofilter as an emission control device, SJVUAPCD Rule 4565 contains detailed requirements for regularly maintaining, monitoring, and testing the biofilter.[93]

Similarly, SCAQMD Rule 1133.2, as adopted January 10, 2003, generally requires operators of "new" co-composting facilities (*i.e.*, those that started operations after January 10, 2003) with design capacities of at least 1,000 tons of throughput per year to conduct all active co-composting within the confines of an enclosure meeting certain conditions, to conduct all curing using an aeration system meeting certain conditions, and to vent the exhaust from the enclosure and aeration system to an emissions control system designed and operated with a control efficiency of at least 80 percent, by weight, for both VOC and ammonia emissions.[94] Alternatively, an operator of a new co-composting facility may submit a compliance plan, for approval by the SCAQMD Executive Officer, that demonstrates an overall emission reduction of 80 percent, by weight, from specified baseline emission factors for both VOC and ammonia emissions.[95] Existing co-composting facilities with design capacities of at least 35,000 tons of throughput per year must submit a compliance plan that demonstrates an overall emission reduction of 70 percent, by weight, from specified baseline emission factors for both VOC and ammonia emissions.[96] For existing facilities or new facilities that elect to submit alternative compliance plans, the compliance plan must specify the operator's selected control method(s), which may include (among others) enclosure design or technology; aeration system design and operation; biofiltration; process controls; or best management practices.[97] According to the final staff report for SCAQMD Rule 1133.2, a well-designed, well-operated, and well-maintained biofilter can achieve 80 percent control efficiency for both VOC and ammonia emissions.[98]

Although SJVUAPCD Rule 4565 does not explicitly require operators of composting/co-composting facilities to achieve specified levels of ammonia emission reductions, as does SCAQMD Rule 1133.2, both rules generally require composting facilities to use enclosures and/or aeration systems vented to an emission control device with a VOC control efficiency of 70 or 80 percent. Given the similarity in the control requirements contained in these rules, we find the requirements of SJVUAPCD Rule 4565 sufficient to satisfy RACM/RACT requirements for ammonia control for the 2006 $PM_{2.5}$ NAAQS.

We also disagree with Earthjustice's claim that the EPA has "proposed to excuse the Plan's failure to analyze ammonia controls" because of the timing of its submission after the D.C. Circuit's decision in *NRDC* v. *EPA*, 706 F.3d 428 (D.C. Cir. 2013). In our proposed rule, we noted that "the timing of the *NRDC* decision in early 2013 may have constrained the State's and District's ability to fully evaluate additional ammonia control measures as part of a RACM/RACT control strategy ahead of the applicable Moderate area attainment date (December 31, 2015)" and stated that we were taking this unique circumstance into account in our evaluation of the Plan.[99] We also noted the absence of specific information regarding more stringent ammonia air emission control measures that may be technologically and economically feasible for implementation in the SJV area and recommended that the State and District conduct a more thorough evaluation of all available ammonia control measures as part of its development of a Serious area plan for the area.[100] The commenter argues generally that the Plan includes no analysis of how the District's rules control ammonia emissions but provides no specific information to show that more stringent control measures are technologically and economically feasible for implementation in the SJV area.

As explained in our proposed rule, sections 172(c)(1) and 189(a)(1)(C) of the Act require that attainment plans for Moderate nonattainment areas provide for the implementation of RACM and RACT for existing sources of $PM_{2.5}$ and $PM_{2.5}$ precursors in the nonattainment area as expeditiously as practicable but no later than 4 years after designation. In longstanding guidance, the EPA has interpreted the RACM requirement to include any potential control measure for a point, area, on-road or non-road emission source that is technologically and economically feasible and is not "absurd, unenforceable, or impracticable."[101] The Act does not require adoption of every conceivable control measure to satisfy the RACM requirement in a Moderate $PM_{2.5}$ nonattainment area.[102] Consistent with the EPA's recommended process for determining RACM/RACT for a given area, the District compiled a list of potential control measures for ammonia emission sources in the SJV; evaluated the identified control measures for "reasonableness," considering technological and economic feasibility and potentially adverse impacts; and identified the SIP-approved control measures in the Plan that it was relying on to implement RACM for ammonia emission sources.[103] Although the Plan does not contain every conceivable control measure for ammonia emissions, we find the control evaluations in the Plan sufficient to demonstrate that it provides for the implementation of all RACM/RACT for ammonia sources that could reasonably be implemented by the statutory implementation deadline under CAA section 189(a)(1)(C) for the 2006 $PM_{2.5}$ NAAQS. We discuss Earthjustice's specific comments about SJVUAPCD Rule 4566 in Response 9 below, and its specific comments about SJVUAPCD Rule 4570 in Response 10 below.

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[88] 2012 $PM_{2.5}$ Plan, Appendix B at B–17 and 2014 Supplement at Attachment A, p. A–1 (indicating that "farming operations" account for 239.2 tpd of ammonia emission and that "waste disposal," which includes composting solid waste operations, accounts for 20.5 tpd of ammonia emissions in 2015, from a total 2015 ammonia inventory of 340.7 tpd).

[89] SJVUAPCD Rule 4565 (adopted March 15, 2007), section 5.3.3 (requiring implementation of at least one "Class Two mitigation measure"); *see also* 2014 Supplement at Attachment A, p. A–36 to A–39.

[90] SJVUAPCD Rule 4565 (adopted March 15, 2007), section 5.3.3 and section 3.3 (defining "alternative mitigation measure").

[91] SJVUAPCD, Final Staff Report, Revised Proposed New Rule 4565 (Biosolids, Animal Manure, and Poultry Litter Operations), March 30, 2007, at p. 9.

[92] SCAQMD, "Technology Assessment for Proposed Rule 1133 (Emission Reductions from Composting and Related Operations)," March 22, 2002, at p. 3–4 and 3–5 ("biofilters use microorganism that live in the biofilm . . . to adsorb and biologically degrade contaminated air into non-harmful substances. In particular, VOC is oxidized to carbon dioxide and water, and ammonia is degraded into nitrate without creating aggravating pollution issues"); *see also* SCAQMD Rule 1133.2 (adopted January 10, 2003), section (c)(5) (defining "biofiltration" as "a pollution control technology that removes and oxidizes VOC and ammonia through the action of bacteria and other microorganisms").

[93] SJVUAPCD Rule 4565 (adopted March 15, 2007), sections 5.5 and 5.7.

[94] SCAQMD Rule 1133.2 (adopted January 10, 2003), section (d)(1).

[95] *Id.* at section (d)(2).

[96] *Id.* at sections (d)(3) and (j)(1).

[97] *Id.* at section (e).

[98] SCAQMD, Final Staff Report, "Proposed Rule 1133—Composting and Related Operations: General Administrative Requirements; Proposed Rule 1133.1—Chipping and Grinding Activities; Proposed Rule 1133.2—Emission Reductions from Co-Composting Operations," January 10, 2003, at p. 18 (stating that "[b]ased on the information collected so far on existing biofilter composting applications, control efficiencies of about 80% to 90% for VOC and 70% to over 90% for ammonia have been achieved. . . . [demonstrating] that a well-designed, well-operated, and well-maintained biofilter is capable of achieving 80 percent control efficiency for VOC and ammonia").

[99] 80 FR 1816, 1830 (January 13, 2015).

[100] *Id.*

Comment 9: Earthjustice disputes the District's finding that its composting rule, Rule 4566, is at least as stringent as SCAQMD Rule 1133.3, and argues that the District failed to consider some of the requirements of SCAQMD Rule 1133.3 in the table that it used to compare the two rules. Earthjustice notes that SCAQMD Rule 1133.3 requires implementation of a mitigation measure that demonstrates emissions reductions, by weight, of at least 40 percent for VOC and at least 20 percent for ammonia, and that SJVUAPCD Rule 4566 requires a mitigation measure that demonstrates emissions reductions of VOC of at least 19 percent, and does not regulate ammonia. While noting that "VOC emissions reductions may result in some ammonia emissions reductions," Earthjustice asserts that because Rule 4566 does not regulate ammonia, the District cannot rely on the rule to result in a certain amount of ammonia emissions.

Response 9: Although SJVUAPCD Rule 4566 does not explicitly regulate ammonia emissions, we disagree with Earthjustice's suggestion that the District cannot rely on this rule as part of its RACM/RACT control strategy for the 2006 $PM_{2.5}$ NAAQS.

SJVUAPCD Rule 4566, as adopted August 18, 2011, requires smaller composting operations to implement at least three turns during active-phase composting and one of several mitigation measures listed in Table 1 of the rule, such as application of water or a finished compost cover, or in the alternative to implement an alternative mitigation measure approved by the APCO and the EPA that demonstrates at least 19 percent reduction, by weight, in VOC emissions.[104] For larger composting operations (*i.e.,* those with a total throughput between 200,000 and 750,000 wet tons per year of organic material), Rule 4566 requires operators to apply both watering and a finished compost cover in addition to implementation of at least three turns during active-phase composting, or in the alternative to implement an alternative mitigation measure approved by the APCO and the EPA that demonstrates at least 60 percent reduction, by weight, in VOC emissions.[105] For the largest composting operations (*i.e.,* those with a total throughput of at least 750,000 wet tons per year of organic material), Rule 4566 requires operators to implement an alternative mitigation measure approved by the APCO and the EPA that demonstrates at least 80 percent reduction, by weight, in VOC emissions.[106]

SCAQMD Rule 1133.3, as adopted July 8, 2011, establishes similar requirements for greenwaste composting operations to periodically turn and water active compost piles and to apply finished compost covers.[107] According to the SCAQMD's staff report for Rule 1133.3, these types of "good composting practices" minimize both VOC and ammonia emissions by balancing the carbon-to-nitrogen ratio and providing adequate aeration and moisture in the compost.[108] As Earthjustice correctly notes, SCAQMD Rule 1133.3 also allows operators of such operations to implement an alternate mitigation measure approved by the SCAQMD Executive Officer, CARB, and the EPA that demonstrates VOC emission reductions by at least 40 percent by weight and ammonia emission reductions by at least 20 percent by weight.[109] For composting operations involving greater than 5,000 tons per year of foodwaste throughput, SCAQMD Rule 1133.3 establishes requirements to conduct the active phase composting using an emission control device designed and operated with an overall system control efficiency of at least 80 percent, by weight, each for VOC and ammonia emissions, or to implement an alternate mitigation measure approved by the SCAQMD Executive Officer, CARB, and the EPA that achieves equivalent reductions in both VOCs and ammonia.[110]

According to CARB, the water management requirements in SJVUAPCD Rule 4566 and SCAQMD Rule 1133.3 achieve an ammonia control efficiency of 19 percent, while use of certain kinds of aerated static piles (ASP) vented to a biofilter achieves an ammonia control efficiency ranging from 20 to 99 percent.[111] In the absence of specific information about more stringent ammonia control requirements for composting operations that the District could reasonably have implemented by the statutory implementation deadline for RACM/RACT in this area (December 14, 2013), we find the requirements of SJVUAPCD Rule 4566 adequate to satisfy RACM/RACT requirements for composting operations for purposes of the 2006 $PM_{2.5}$ NAAQS in the SJV.

Comment 10: Earthjustice comments that the District did not adequately review Rule 4570 (Confined Animal Facilities) when it compared it to similar rules in other California districts and the state of Idaho. According to

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[101] 80 FR 1816, 1826 (January 13, 2015) (citing "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990," 57 FR 13498 (April 16, 1992) (General Preamble) at 13540, 13560).

[102] *See* 55 FR 38326 (September 18, 1990) (revoking prior EPA guidance to the extent it suggested or stated that areas with severe pollution problems must implement every conceivable control measure including those that would cause severe socioeconomic disruption to satisfy RACM).

[103] 2014 Supplement at Attachment A (ammonia controls).

[104] SJVUAPCD Rule 4566 (adopted August 18, 2011), section 5.2.1.

[105] *Id.* at section 5.2.2.

[106] *Id.* at section 5.2.3.

[107] SCAQMD Rule 1133.3 (adopted July 8, 2011), section (d)(2).

[108] SCAQMD, Final Staff Report, "Proposed Amended Rule 1133.1—Chipping and Grinding Activities; Proposed Rule 1133.3—Emission Reductions from Greenwaste Composting Operations," July 2011, at p. 3 ("[g]ood composting practices, which balance the carbon-to-nitrogen (C:N) ratio and provide adequate aeration and moisture, will minimize VOC, ammonia and GHG emissions").

[109] SCAQMD Rule 1133.3 (adopted July 8, 2011), section (d)(2)(E).

[110] *Id.* at section (d)(3).

[111] CARB, "ARB Emissions Inventory Methodology for Composting Facilities" (posted 2015) at Table III–3 ("Control Techniques for Composting Operations"), available at *http://www.arb.ca.gov/ei/areasrc/Composting%20Emissions%20Inventory%20Methodology%20Final%20Combined.pdf.*

Earthjustice, SJVUAPCD Rule 4570 and Idaho's rule "employ drastically different methods to reduce emissions from dairies," and the District has not fully explored aspects of the Idaho rule that could strengthen SJVUAPCD Rule 4570. In particular, Earthjustice asserts that the District misconstrued a statement by the Idaho Department of Environmental Quality (Idaho DEQ) that described the Idaho rule as employing an "arbitrary" point system. According to Earthjustice, the maximum number of points in the system's rating scale was "arbitrary" in the sense that another number could have been selected, but the Idaho DEQ "thoroughly analyzed the control measures and their associated ammonia emission reductions," and allocated points based on these reductions. Because the District has not done a similar evaluation of the measures in SJVUAPCD Rule 4570, Earthjustice asserts, it has not fully compared the stringency of the rule against the Idaho rule.

Earthjustice asserts that the District's comparison of the stringency of SJVUAPCD Rule 4570 and other California air district rules is insufficient because the District considered only the number of mitigation measures required by each district. Earthjustice states that the District should consider instead the ammonia emissions reductions achieved under each rule. Further, Earthjustice states, if the District finds that other air districts' mitigation measures are more effective in reducing emissions, it should incorporate those measures into its rule.

Response 10: We agree that the District appears to have misconstrued the Idaho DEQ's statement about the point system in Idaho Rule 58.01.01, sections 760–764 (Rules for the Control of Ammonia from Dairy Farms) (hereafter "Idaho CAF Rule") and that the District should have considered the ammonia emission reductions achieved under the rules that it evaluated, rather than simply addressing the number of mitigation measures required in each rule. For the reasons provided below, however, we find SJVUAPCD Rule 4570 adequate to satisfy RACM/RACT requirements for the 2006 $PM_{2.5}$ NAAQS in the SJV.

SJVUAPCD Rule 4570, as amended October 21, 2010, requires that CAFs of certain sizes for dairy cows, other cattle, swine, poultry, and layer hens implement measures to reduce VOC emissions during feed operations, manure management and other CAF processes.[112] Both VOCs and ammonia are emitted during these activities at CAFs. Given the large proportion of ammonia emissions that come from cow manure produced at CAFs,[113] we focus our evaluation below on measures to reduce ammonia from the production and handling of cow manure at dairy CAFs.

Ammonia emissions from CAF manure processes may be reduced by flushing lanes in freestall barns[114] and limiting manure exposure to air through land incorporation.[115] According to the SJVUAPCD, freestall barns are the largest source of manure at SJV dairies.[116] Rule 4570 contains mandatory requirements for all dairy CAFs subject to the rule that house animals in freestalls to frequently clean the housing flush lanes—specifically, to "flush or scrape freestall flush lanes at least three (3) times per day" or to "flush, scrape, or vacuum freestall flush lanes" immediately before, after, or during each milking.[117] In practice, most CAFs in the SJV comply with the SJVUAPCD Rule 4570 manure management requirements by flushing manure to dilute the urea in urine, which reduces ammonia emissions,[118] and by incorporating solid manure into crop land within 72 hours of land application.[119]

In addition, SJVUAPCD Rule 4570 requires each owner/operator of a large dairy CAF that handles or stores solid manure or separated solids outside the animal housing to remove dry manure or separated solids from the facility or cover it with a weatherproof covering from October through May, within 72 hours of collecting it, or to implement an "alternative mitigation measure"[120] approved by CARB and the EPA.[121] SJVUAPCD Rule 4570 provides, in Table 4.1.H, specific requirements for applying manure to agricultural lands on the facility including the option to incorporate all solid manure within 72 hours.

We are aware of only two rules implemented in other areas that explicitly regulate ammonia emissions from dairy facilities—the Idaho CAF Rule and SCAQMD Rule 1127 (Emission Reductions from Livestock Waste).[122] The Idaho CAF Rule assigns points to each ammonia mitigation measure listed in the rule and requires dairy farm operators to implement measures that collectively achieve at least 27 points.[123] The rule only applies, however, to dairy farms containing between 1,638 and 5,063 cows, depending on the type of dairy facility.[124] SJVUAPCD Rule 4570, on the other hand, applies to dairy CAFs containing at least 500 milking cows and also applies to other types of CAFs, including beef cattle feedlots, other cattle facilities, poultry facilities, and swine facilities.[125] As we stated in our proposed rule, because the structure of the Idaho CAF Rule differs substantially from the structure of SJVUAPCD Rule 4570, it is difficult to compare the requirements in these two rules directly.[126]

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[112] *See generally* SJVUAPCD Rule 4570 (amended October 21, 2010).

[113] "Ammonia Emissions and Animal Agriculture," Susan W. Gay and Katharine F. Knowlton, Virginia Cooperative Extension, Virginia Tech, 2009 (noting that "[a]mmonia is a common by-product of animal waste due to the often inefficient conversion of feed nitrogen into animal product. Livestock and poultry are often fed high-protein feed, which contains surplus nitrogen, to ensure that the animals' nutritional requirements are met. Nitrogen that is not metabolized into animal protein (*i.e.*, milk, meat, or eggs) is excreted in the urine and feces of livestock and poultry where further microbial action releases ammonia into the air during manure decomposition").

[114] W. Kroodsma, J.W.H. Huis In 't Veld & R. Scholtens, 1993, "Ammonia emissions and its reduction from cubicle houses by flushing," Livestock Production Science 35: 293–302.

[115] Ndegwa, P.M., A.N. Hristov, J. Arogo, and R.E. Sheffield, "A review of ammonia emission mitigation techniques for concentrated animal feeding operations," J. Bioengineering Systems, ed. 100, 2008, p. 463–464.

[116] SJVUAPCD, Final Staff Report: Rule 4570 (October 21, 2010), at p. 9.

[117] SJVUAPCD Rule 4570 (amended October 21, 2010) at Section 5.6.1 and Table 4.1.D.2. Milking generally occurs at least twice a day at a typical dairy CAF. *See* Walter L. Hurley, Lactation Biology Web site, ANSC 438, University of Illinois, available at ***http://ansci.illinois.edu/static/ansc438/ Lactation/milkingfrequency.html.***

[118] Memorandum dated June 15, 2016, from Andy Steckel to Kerry Drake, EPA Region 9, "Summary of our 6/10/16 Discussion with Kevin Abernathy, Milk Producers Council" and W. Kroodsma, et al., 1993, "Ammonia emissions and its reduction from cubicle houses by flushing," Livestock Production Science 35: 293–302, at p. 300 (noting that "[f]lushing has a significant emission reducing effect [because] . . . the urea concentration on slats, concrete floors and in the top layer of the slurry is lowered by dilution"); *see also* SJVUAPCD, Final Staff Report: Rule 4570 (October 21, 2010), at p. 10 (noting that "[l]iquid systems are common in large dairies due to their lower labor costs and ease of use with automatic flushing systems").

[119] Memorandum dated June 15, 2016, from Andy Steckel to Kerry Drake, EPA Region 9, "Summary of our 6/10/16 Discussion with Kevin Abernathy, Milk Producers Council"; *see also* email dated June 9, 2016, from Samir Sheikh of the SJVUAPCD to Kerry Drake of EPA Region 9, regarding "Manure Land Application."

[120] "Alternative Mitigation Measure" is defined in Rule 4570 as "a mitigation measure that is determined by the APCO, CARB, and EPA to achieve reductions that are equal to or exceed the reductions that would be achieved by other mitigation measures listed in this rule that owners/ operators could choose to comply with rule requirements." SJVUAPCD Rule 4570 (amended October 21, 2010), Section 3.4.

[121] SJVUAPCD Rule 4570 (amended October 21, 2010), Section 5.6.1 at Table 4.1.F.

[122] *See* Idaho Administrative Code 58.01.01, section 760, and SCAQMD Rule 1127 (adopted August 6, 2004), paragraph (a). Other CAF rules in California include SCAQMD Rule 223, BAAQMD Rule 2–10, SMAQMD Rule 496, VCAPCD Rule 23, Imperial County APCD (ICAPCD) Rule 217, and Butte County AQMD Rule 450. Each of these rules also regulates CAFs but does not establish specific requirements for ammonia control. For example, SCAQMD Rule 223 (adopted June 2, 2006) identifies ammonia as a precursor to particulates, but its requirements are very similar to SJVUAPCD Rule 4570 as originally adopted June 15, 2006. Similarly, ICAPCD Rule 217 states that its purpose is to limit emissions of VOC and ammonia, but the mitigation requirements are generally equivalent to those in SJVUAPCD Rule 4570.

[123] Idaho Administrative Code 58.01.01, section 764, paragraph 01 ("Dairy farm best management practices") (requiring dairies to "employ BMPs for the control of ammonia to total twenty-seven (27) points").

Additionally, according to information submitted by the SJVUAPCD, the option in the Idaho CAF Rule to cover synthetic lagoons (one of the key mitigation measures in the rule) would not be effective in the SJV and could increase ammonia emissions at CAFs in the SJV.[127] Furthermore, the Idaho CAF Rule states that "[p]oints may be obtained through third party export with sufficient documentation" and that "[a]s new information becomes available or upon request, the Director may determine a practice not listed in the table constitutes a BMP and assign a point value." [128] These ambiguously phrased provisions allow CAF owners/operators to comply with the rule by implementing measures entirely different from those listed in the rule that may or may not be effective in reducing ammonia emissions. The commenter has provided no information to support a conclusion that the requirements of the Idaho CAF Rule will actually achieve ammonia emission reductions, nor any information to indicate that the requirements of this rule are more stringent than those in SJVUAPCD Rule 4570.

SCAQMD Rule 1127, as adopted August 6, 2004, applies only to livestock waste (*i.e.*, manure management) at dairy farms and related operations. Unlike SJVUAPCD Rule 4570, which explicitly requires that dairy CAFs regularly flush, scrape, or vacuum freestall flush lanes,[129] SCAQMD Rule 1127 contains no analogous requirement to regularly clean flush lanes in freestall barns.[130] SCAQMD Rule 223, as adopted June 2, 2006, contains menu-based options for flushing, scraping, or vacuuming freestall barns but does not specifically mandate such measures.[131]

Additionally, SCAQMD Rule 1127 requires that a dairy operator disposing of manure within the South Coast area remove or contract to remove the manure to a manure processing operation approved in accordance with specific requirements and/or to agricultural land within the SCAQMD approved by local ordinance and/or the regional water quality board for the spreading of manure.[132] Rule 1127 does not require that manure be incorporated into agricultural land within any specific timeframe to reduce ammonia emissions.

Thus, neither SJVUAPCD Rule 4570 nor SCAQMD Rule 1127 strictly requires dairy CAF operators to promptly remove and dispose of collected manure to minimize ammonia emissions. The commenter has failed to identify any measure implemented in the South Coast or elsewhere that is more stringent than the requirements of SJVUAPCD Rule 4570 for this particular component of the manure handling process.

On balance, we find that SJVUAPCD Rule 4570 is more stringent than the Idaho CAF Rule and SCAQMD Rule 1127 given SJVUAPCD Rule 4570 establishes specific requirements for the frequency of flushing manure from freestall barns, which are a significant source of manure and ammonia emissions at dairy CAFs in SJV, while the Idaho CAF Rule and SCAQMD Rule 1127 contain no analogous requirements. In the absence of specific information about more stringent ammonia control requirements for CAFs that the District could reasonably have implemented by the statutory implementation deadline for RACM/RACT in this area (December 14, 2013), we find the requirements of SJVUAPCD Rule 4570 adequate to satisfy RACM/RACT requirements for CAFs for purposes of the 2006 $PM_{2.5}$ NAAQS in the SJV.

Comment 11: Earthjustice argues that the RACM/RACT demonstration fails to comply with CAA section 189(a)(1)(C), which requires a plan to include provisions to assure that RACM is implemented no later than four years after a moderate nonattainment designation. Earthjustice asserts that this section required the District to implement RACM for the 2006 $PM_{2.5}$ standards by December 14, 2013. According to Earthjustice, because the District has not implemented controls identified by Earthjustice as RACM/RACT and has delayed additional charbroiling and residential furnace controls, the EPA must disapprove the demonstration and place the District on a clock to ensure that the missing measures are adopted expeditiously.

Response 11: We disagree. Section 107(a) of the CAA provides states with both the authority and primary responsibility to develop SIPs that meet applicable statutory and regulatory requirements for attaining, maintaining, and enforcing the NAAQS. States have discretion in formulating their SIPs, and the EPA is required to approve a SIP submission that satisfies the applicable requirements of the Act.[133]

As the commenter notes, CAA section 189(a)(1)(C) requires that each attainment plan for a Moderate $PM_{2.5}$ nonattainment area include provisions to assure that RACM for the control of $PM_{2.5}$ and $PM_{2.5}$ precursors are implemented no later than four years after the area's designation as nonattainment. For the SJV area, the deadline for implementation of RACM for the 2006 $PM_{2.5}$ NAAQS under CAA section 189(a)(1)(C) was December 14, 2013. For the reasons provided in our proposed rule and further explained above in Response 6 through Response 10, we conclude that the 2012 $PM_{2.5}$ Plan and 2014 Supplement provide for the implementation of all RACM/RACT that could reasonably be implemented in the SJV by the statutory implementation deadline, as required by CAA sections 172(c) and 189(a)(1)(C).

Additionally, we disagree with the commenter's assertion that revisions to SJVUAPCD Rule 4901 ("Wood Burning

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[124] *Id.* at section 761 ("General applicability").

[125] SJVUAPCD Rule 4570 (amended October 21, 2010), Table 2 and Section 5.6.

[126] 80 FR 1816, 1829–30 (January 13, 2015) (noting, for example, that the Idaho CAF Rule identifies certain mitigation measures that are not included in SJVUAPCD Rule 4570, while Rule 4570 contains more stringent applicability thresholds and provisions for testing and records retention).

[127] Email dated June 25, 2015 from Sheraz Gill of the SJVUAPCD to Andrew Steckel of EPA Region 9, regarding "Requested Information" and attachment, "Evaluation of Covers Lagoons Manure Piles for NH_3.pdf."

[128] Idaho Administrative Code 58.01.01, at section 764–01 ("BMPs").

[129] SJVUAPCD Rule 4570 (amended October 21, 2010) at Section 5.6.1 and Table 4.1.D.2. Milking generally occurs at least twice a day at a typical dairy CAF. Walter L. Hurley, Lactation Biology Web site, ANSC 438, University of Illinois at *http://ansci.illinois.edu/static/ansc438/Lactation/milkingfrequency.html.*

[130] SCAQMD Rule 1127 does require dairies to remove manure accumulated in corrals at least 4 times per year and to remove manure stockpiles within 3 months of the last corral clearing day, and no more than 3 months after the date that previous stockpiles were last completely cleared. SCAQMD Rule 1127 (adopted August 6, 2004), sections (d)(4) and (d)(5).

[131] SCAQMD Rule 223, Appendix A, Table 1.C (requiring owners/operations at large dairy CAFs that house animals in freestall barns to implement at least 2 of 9 listed mitigation measures, including measures to regularly flush, scrape or vacuum freestalls).

[132] *Id.* at section (e).

[133] CAA section 110(k)(3), 42 U.S.C. 7410(k)(3) and 40 CFR 52.02(a); *see also Union Elec. Co.* v. *EPA*, 427 U.S. 246, 250 (1976); *Train* v. *Natural Res. Def. Council*, 421 U.S. 60, 79 (1975).

Fireplaces and Wood Burning Heaters") are necessary to satisfy RACM requirements for the 2006 $PM_{2.5}$ NAAQS in the SJV. *See* Response 6.d. Similarly, we disagree with the commenter's assertion that SJVUAPCD Rule 4692 (Commercial Charbroiling) fails to satisfy RACM requirements for the 2006 $PM_{2.5}$ NAAQS in the SJV. *See* Response 6.e.

Comment 12: Earthjustice argues that much of the Plan's control strategy is unenforceable and that this is inconsistent with CAA section 110(a)(2)(A), which requires SIPs to "include enforceable emissions limitations and other control measures." Specifically, Earthjustice argues that three control strategies challenged in recent litigation are not enforceable: (1) Mobile sources measures that are not included in the SIP; (2) open-ended tonnage commitments; and (3) voluntary incentive programs.

Comment 12a: Mobile source "waiver" measures. Earthjustice notes that a significant portion of the emissions reductions in the Plan come from state mobile source measures for which the EPA has issued a waiver under CAA section 209. Earthjustice argues that because these measures are not included in the SIP, they are not enforceable by either the EPA or citizens, and therefore do not meet the requirements of CAA section 110(a)(2)(A).

Earthjustice also criticizes the EPA's general policy of not including these "waiver measures" in the SIP. Earthjustice argues that requiring the EPA to approve waiver measures into the SIP is not inconsistent with Congress' intent to provide California with "the broadest possible discretion" to develop mobile source measures, and that there is no conflict between CAA sections 110 and 209 that would prevent the EPA from adding these measures to the SIP. Additionally, Earthjustice argues that Congress has not ratified the EPA's policy of excluding waiver measures from SIPs, asserting that the EPA had not affirmatively expressed its policy until recently and that the agency has contradicted this policy in previous statements.

Response 12a: The EPA has historically allowed California to take credit for measures for which the state has obtained a waiver of federal preemption under CAA section 209 ("waiver" measures) even though the waiver measures themselves (*i.e.,* CARB's regulations) had not been adopted and approved as part of the California SIP. However, a recent decision by the Ninth Circuit Court of Appeals held that the EPA's longstanding practice in this regard was at odds with the CAA requirement that state and local emissions limits relied upon to meet the NAAQS be enforceable by the EPA or private citizens through adoption and approval of such limits in the SIP.[134]

In response to the court's decision, CARB has adopted the necessary waiver measures as revisions to the California SIP and submitted them to the EPA for approval.[135] The EPA proposed to approve the waiver measures into the California SIP at 80 FR 69915 (November 12, 2015) and took final action to approve these measures into the SIP at 81 FR 39424 (June 16, 2016). Accordingly, these waiver measures are now enforceable by the EPA or private citizens under the CAA, consistent with the enforceability requirement in CAA section 110(a)(2)(A).

Comment 12b: Open-ended commitments. Earthjustice asserts that the District's commitment to reduce direct $PM_{2.5}$ by 1.9 tons per day (tpd) by 2019 is not enforceable. According to Earthjustice, although the District has committed to proposing certain measures to its board, it has not specified when it will implement those measures or committed to achieving reductions as a result of the measures. Earthjustice characterizes these measures as "goals" that have been found by courts to be unenforceable, citing *Bayview Hunters Point Community Advocates* v. *Metropolitan Transportation Commission,* 366 F.3d 692 (9th Cir. 2004). According to Earthjustice, it will be "virtually impossible" for either citizens or the EPA to determine whether the District has in fact met its 2019 reduction target, citing the EPA's statement at 57 FR at 13,568 that "[a] regulatory limit is not enforceable if, for example, it is impractical to determine compliance with the published limit." Additionally, citing CAA section 182(e)(5), Earthjustice asserts that the CAA allows "open-ended commitments" only in limited circumstances and that there is no parallel provision for creating such a "black box" in $PM_{2.5}$ plans.

Response 12b: We disagree with the commenter's claim that the District's commitments in the 2012 $PM_{2.5}$ Plan are not enforceable. We also disagree with the commenter's suggestion that the long-term strategy provision for ozone attainment plans in CAA section 182(e)(5) is the only statutory provision that allows for approval of attainment plans that rely on state commitments, and that commitments such as those identified in the 2012 $PM_{2.5}$ Plan are not permissible in $PM_{2.5}$ attainment plans.

Section 182(e)(5) of the CAA authorizes the EPA to approve provisions of an attainment plan for an extreme ozone nonattainment area that anticipate development of new control techniques or improvement of existing control technologies, and to approve an attainment demonstration based on such provisions, if, *inter alia,* the State has submitted enforceable commitments to submit adopted contingency measures meeting certain criteria no later than three years before proposed implementation of the new technology measures.[136] Contrary to the commenter's suggestion, section 182(e)(5) is not the only provision in the CAA that allows for approval of attainment plans that rely on enforceable commitments. Sections 110(a)(2)(A) and 172(c)(6) of the CAA require that SIPs include enforceable emission limitations and such other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for attainment of the NAAQS by the applicable attainment date. For over 20 years, the EPA has consistently maintained its interpretation of these provisions as allowing for approval, under certain circumstances, of a SIP that contains an enforceable commitment to adopt additional controls as part of a comprehensive control strategy for attaining the NAAQS.[137] The EPA's interpretation of the Act as allowing for approval of limited enforceable commitments has been upheld by several courts of appeals.[138]

As explained in our proposed rule, we generally consider three factors in determining whether to approve the use of an enforceable commitment to meet a CAA requirement: (1) Does the commitment address a limited portion of the CAA-required program; (2) is the state capable of fulfilling its commitment; and (3) is the commitment for a reasonable and appropriate period of time. We stated in our proposed rule that we were not evaluating the commitments in the 2012 $PM_{2.5}$ Plan in accordance with this three-factor test because the Plan did not rely on any of these commitments to satisfy CAA requirements.[139] In response to these comments, however, we have evaluated the commitments in the 2012 $PM_{2.5}$ Plan to amend SJVUAPCD Rule 4308 in 2013 and to adopt Rule 4905 in 2014 in accordance with our three-factor test, because these commitments were part of the control strategy to be implemented prior to the Moderate area attainment date (December 31, 2015) for the 2006 $PM_{2.5}$ NAAQS in the SJV area.[140] We find that these commitments satisfy the EPA's three-factor test as follows: (1) The commitments address a limited portion of the CAA-required program because the Plan relies on them only to supplement the RACM and RFP control strategies in the impracticability demonstration and does not rely on either commitment for necessary emission reductions; (2) the state has fulfilled both commitments, as explained further below in this response; and (3) each commitment was for a reasonable and appropriate period of time—*i.e.*, to be fulfilled by 2013 and 2014, ahead of the December 31, 2015 Moderate area attainment date. Accordingly, we are approving the District's commitment to amend Rule 4308 as a RACM and approving the District's commitment to adopt Rule 4905 in 2014 as an additional reasonable measure under CAA section 172(c)(6).[141]

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[134] See *Committee for a Better Arvin* v. *EPA,* 786 F.3d 1169 (9th Cir. 2015).

[135] See letter dated August 14, 2015, from Richard W. Corey, Executive Officer, California Air Resources Board, to Jared Blumenfeld, Regional Administrator, EPA Region 9, with attachments.

[136] CAA section 182(e)(5).

[137] *See, e.g.,* 62 FR 1150, 1187 (Jan. 8, 1997) (approving ozone attainment demonstration for the South Coast Air Basin); 65 FR 18903 (Apr. 10, 2000) (approving revisions to ozone attainment demonstration for the South Coast Air Basin); 63 FR 41326 (Aug. 3, 1998) (promulgating federal implementation plan for PM–10 for Phoenix); 69 FR 30005 (May 26, 2004) (approving PM–10 attainment demonstration for San Joaquin Valley); 48 FR 51472 (approving ozone attainment demonstration for New Jersey).

[138] *See, e.g., City of Seabrook* v. *EPA,* 659 F.2d 1349 (5th Cir. 1981); *Connecticut Fund for the Environment* v. *EPA,* 672 F.2d 998 (2d Cir.), cert. denied 459 U.S. 1035 (1982); *BCCA Appeal Group* v. *EPA,* 355 F.3d 817 (5th Cir. 2003), *reh'g denied,* 2004 U.S. App. LEXIS 215 (5th Cir., January 8, 2004); *Environmental Defense* v. *EPA,* 369 F.3d 193, 209 (2d Cir. 2004); and *Committee for a Better Arvin* v. *EPA,* 786 F.3d 1169 (9th Cir. 2015) (upholding EPA approval of CARB and SJVUAPCD commitments as enforceable SIP measures consistent with requirements of CAA section 110(a)(2)(A)).

We also find that the commitments are enforceable and therefore appropriate for approval under CAA section 110.[142] Specifically, SJVUAPCD Governing Board Resolution 2012–12–19 states:

> The District Governing Board commits to adopt and implement the rules and measures in the Plan by the dates specified in Chapter 5 to achieve the emissions reductions shown in Chapter 5, and to submit these rules and measures to ARB within 30 days of adoption for transmittal to EPA as a revision to the State Implementation Plan (SIP). If the total emission reductions from the adopted rules are less than those committed to in the Plan, the District Governing Board commits to adopt, submit, and implement substitute rules that will achieve equivalent reductions in emissions of direct $PM_{2.5}$ or $PM_{2.5}$ precursors in the same adoption and implementation timeframes or in the timeframes needed to meet CAA milestones.[143]

Chapter 5 of the 2012 $PM_{2.5}$ Plan identifies, in Table 5–3, the "regulatory control measure commitments" and related amendment dates, compliance dates, and amounts of emission reductions shown in Table 5.

TABLE 5—SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT, 2012 $PM_{2.5}$ PLAN, SPECIFIC RULE ADOPTION/AMENDMENT COMMITMENTS

Rule number	Rule title	Amendment date	Compliance date	Emission reductions
4308	Boilers, Steam Generators, and Process Heaters 0.075 to <2 MMBtu/hr [144].	2013	2015	TBD.
4692	Commercial Charbroiling	2016	2017	0.4 tpd $PM_{2.5}$.
4901	Wood Burning Fireplaces and Wood Burning Heaters	2016	2016/2017	1.5 tpd of $PM_{2.5}$.
4905	Natural Gas-Fired, Fan-Type Residential Central Furnaces	2014	2015	TBD.
9610	SIP Creditability of Incentives	2013	2013	TBD.

Source: 2012 $PM_{2.5}$ Plan, Chapter 5, Table 5–3 ("Regulatory Control Measure Commitments").

Thus, the District Governing Board's commitment specifies the actions the Board committed to undertake, the dates by which it would take such actions, and the emission reductions (if any) that it would achieve through these actions. We find these commitments specific enough to be enforced by the EPA or by citizens under the CAA and are, therefore, approving them into the California SIP.

We note that the SJVUAPCD has made substantial progress on satisfying the commitments identified in the Plan, as follows:

Rule 4308. The District amended SJVUAPCD Rule 4308 on November 14, 2013, and CARB submitted it to the EPA for SIP action on May 13, 2014. The EPA approved amended SJVUAPCD Rule 4308 at 80 FR 7813 (February 12, 2015).

Rule 4905. The District adopted Rule 4905 on January 22, 2015, and CARB submitted the rule to the EPA for SIP action on April 7, 2015. The EPA approved Rule 4905 at 81 FR 17390 (March 29, 2016).

Rule 9610. The District adopted Rule 9610 on June 20, 2013, and CARB submitted the rule to the EPA for SIP action on June 26, 2013. The EPA finalized a limited approval and limited disapproval of Rule 9610 at 80 FR 19020 (April 9, 2015).

Rule 4901. The District amended Rule 4901 on September 18, 2014, and CARB submitted the rule to the EPA for SIP action on November 6, 2014. On August 15, 2016, Acting Regional Administrator Alexis Strauss signed a notice of final rulemaking to approve SJVUAPCD Rule 4901.[145]

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[139] 80 FR 1816, 1833 (January 13, 2015).

[140] We did not evaluate the District's commitments to amend Rule 4692 and Rule 4901 in 2016 or to achieve an aggregate reduction of 1.9 tpd of direct $PM_{2.5}$ by 2019 in accordance with our three-factor test because these commitments address actions to be undertaken after the Moderate area attainment date (December 31, 2015) and, therefore, are not part of the control strategy for this impracticability demonstration. Additionally, we did not evaluate the District's commitment to adopt Rule 9610 in 2013 in accordance with our three-factor test because this rule is not a control measure and therefore is not eligible for SIP emission reduction credit. *See* Response 12c, *infra.*

[141] The District's commitment to adopt Rule 4905 in 2014 does not qualify as a RACM because it is a measure implemented after the RACM implementation deadline (December 14, 2013). It is, however, an additional measure implemented before the Moderate area attainment date (December 31, 2015) and therefore may be treated as part of the Moderate area control strategy for the area under CAA section 172(c)(6).

[142] *See Committee for a Better Arvin* v. *EPA,* 786 F.3d 1169 (9th Cir. 2015) (upholding EPA approval of CARB and SJVUAPCD commitments as enforceable SIP measures consistent with requirements of CAA section 110(a)(2)(A)).

[143] SJVUAPCD Governing Board Resolution 2012–12–19, "In the Matter of: Adopting the San Joaquin Valley Unified Air Pollution Control District 2012 $PM_{2.5}$ Plan."

[144] "MMBtu" means million British Thermal Units.

Comment 12c: Voluntary incentive programs. Earthjustice states that the EPA's suggestion that Rule 9610 (State Implementation Plan Credit for Emission Reductions Generated Through Incentive Programs) may provide emission reductions to help satisfy the District's tonnage commitment is particularly confusing. Earthjustice understands the EPA's proposed approval of Rule 9610 and related technical support document to say that an incentive program's compliance with the rule's SIP-creditability definitions does not mean that the incentive program is, in fact, SIP-creditable. Thus, Earthjustice states, commenters "do not understand how Rule 9610 itself will provide any creditable emission reductions."

More fundamentally, Earthjustice asserts, the emissions reductions that may be achieved through the District's incentive programs cannot be credited in a SIP unless they are treated under the EPA's voluntary emissions reductions policy. Earthjustice states that "[t]he requirement to reduce emissions in exchange for incentive funding is not enshrined in any sort of control measure that is included in the [SIP] and enforceable by EPA or citizens" and that, as with "waiver measures," approval of a strategy built upon these reductions would (again) violate Clean Air Act section 110(a)(2)(A)."

Response 12c: We agree with Earthjustice's statement that SJVUAPCD Rule 9610 itself is not a SIP-creditable control measure and that the District therefore cannot rely on this rule to satisfy any SIP emission reduction commitments.

SJVUAPCD Rule 9610, as adopted June 20, 2013, establishes a regulatory framework for the District's quantification of emission reductions achieved through incentive programs and provides opportunities for the EPA, CARB, and the public to review and comment on the District's evaluations on an annual basis. As we stated in our May 19, 2014 proposal to approve Rule 9610, the rule "does not establish any emission limitation, control measure, or other requirement that applies directly to an emission source" and therefore "is not intended to implement the reasonably available control technology (RACT) standard or any other control standard under the Act."[146] Instead, Rule 9610 "establishes an administrative mechanism designed to ensure that each SIP submittal in which the District relies upon emission reductions achieved through implementation of incentive programs in the SJV will adequately address the requirements of the Act."[147] The requirements and procedures in Rule 9610 apply only to the District and lay the groundwork for the District's incorporation of incentive programs into air quality plans going forward.[148] The EPA finalized a limited approval and limited disapproval of Rule 9610 on April 9, 2015, thereby making its requirements and procedures enforceable by the EPA or citizens against the District.[149]

As part of our proposed action on the 2012 $PM_{2.5}$ Plan, we listed SJVUAPCD Rule 9610 among the District's rule amendment commitments[150] and explained that the District had committed to adopt, submit, and implement Rule 9610 to "provide a *process* for quantifying emissions reductions from the use of incentive funds."[151] To the extent our proposed rule suggested that SJVUAPCD Rule 9610 may itself be a SIP-creditable control measure, we hereby clarify that this rule does not achieve any SIP-creditable emission reductions and therefore cannot be credited for any SIP purpose.

Additionally, to the extent Earthjustice intended to assert that emissions reductions achieved through a state or local incentive program cannot be credited in a SIP except through a SIP submission that satisfies the requirement of the Act as interpreted in EPA guidance, we agree. As we explained in our final action on SJVUAPCD Rule 9610:

> We expect the District to address the applicable requirements of the CAA in each individual SIP submittal that relies on incentive programs, and our recommendations in both the proposal and today's final rule are intended to provide the District with general guidance on how these requirements, as interpreted in EPA guidance, apply to future SIP submittals developed pursuant to Rule 9610 and the requirements of the Act. . . . EPA will review each SIP submittal developed pursuant to Rule 9610 (including the necessary evaluation of the applicable incentive program guidelines) on a case-by-case basis, following notice-and-comment rulemaking, to determine whether the applicable requirements of the Act are met [*internal citations omitted*]. Nothing in today's action prohibits EPA from disapproving a SIP relying on incentive-based emission reductions that fails to satisfy the requirements of the CAA.[152]

With respect to Earthjustice's statement that "[t]he requirement to reduce emissions in exchange for incentive funding is not enshrined in any sort of control measure that is included in the [SIP] and enforceable by EPA or citizens," we note that under longstanding EPA guidance, SIP credit may be allowed for a voluntary or other nontraditional measure only where the State submits enforceable mechanisms to ensure that the emission reductions necessary to meet applicable CAA requirements are achieved—*e.g.,* an enforceable commitment to monitor and report on emission reductions achieved and to rectify any shortfall in a timely manner.[153] Thus, if California intends to satisfy a SIP requirement through reliance on an incentive program that the EPA and citizens may not directly enforce against participating sources, the State/District must take responsibility for assuring that SIP emission reduction requirements are met through an enforceable commitment, which the EPA and citizens may enforce against the State/District upon the EPA's approval of the commitment into the SIP.[154] Approval of a control strategy built upon emission reductions achieved through incentive programs may satisfy CAA section 110(a)(2)(A) only if these enforceability requirements are met.[155]

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[145] EPA, Final Rule, "Approval of California Air Plan Revisions, San Joaquin Valley Unified Air Pollution Control District," August 15, 2016 (pre-publication notice).

[146] 79 FR 28650, 28652 and n. 5 (May 19, 2014).

[147] *Id.*

[148] *Id.*

[149] 80 FR 19020 (April 9, 2015) (concluding that Rule 9610 largely satisfies CAA requirements but contains several deficiencies warranting limited disapproval).

[150] 80 FR 1816 at 1827 (Table 2), 1832 (Table 3).

[151] 80 FR 1816, 1831 (emphasis added).

[152] 80 FR 19020, 19022 (April 9, 2015).

[153] *Id.* at 19026.

[154] *Id.*

[155] The EPA has recommended presumptive limits on the amounts of emission reductions from certain voluntary and other nontraditional measures that may be credited in a SIP. Specifically, for voluntary mobile source emission reduction programs (VMEPs), the EPA has identified a presumptive limit of three percent (3%) of the total projected future year emission reductions required to attain the appropriate NAAQS, and for any particular SIP submittal to demonstrate attainment or maintenance of the NAAQS or progress toward attainment (*e.g.,* RFP), 3% of the specific statutory requirement. *See, e.g.,* "Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs)," EPA, Office of Air and Radiation (OAR), October 24, 1997, at 5 and "Improving Air Quality with Economic Incentive Programs," EPA, OAR, January 2001, at 158. For voluntary stationary and area source measures, the EPA has identified a presumptive limit of 6% of the total amount of emission reductions required for RFP, attainment, or maintenance demonstration purposes. *See, e.g.,* "Incorporating Emerging and Voluntary Measures in a State Implementation Plan," EPA, OAR, September 2004 ("2004 Emerging and Voluntary Measures Guidance") at 9 and "Incorporating Bundled Measures in a State Implementation Plan (SIP)," August 2005 ("2005 Bundled Measures

Guidance''), at 8. The EPA has also long stated, however, that states may justify higher amounts of SIP emission reduction credit for voluntary programs on a case-by-case basis, and that the EPA may approve measures for SIP credit in excess of the presumptive limits "where a clear and convincing justification is made by the State as to why a higher limit should apply in [its] case." 2004 Emerging and Voluntary Measures Guidance at 9; *see also* 2005 Bundled Measures Guidance at 8, n. 6 and "Diesel Retrofits: Quantifying and Using Their Emission Benefits in SIPs and Conformity," EPA, OTAQ, February 2014, at 12.

D. Comments on RFP, RFP Contingency Measures, and Quantitative Milestones

Comment 13: Earthjustice disagrees with the EPA's proposal to approve the RFP demonstration in the Plan, quoting the statutory definition of "reasonable further progress" in CAA section 171(1) and asserting that the EPA's approach to RFP "divorces the RFP targets from attainment altogether by claiming that the RFP requirement of CAA section 172(c)(2) can be met by assuring implementation of RACM/RACT." Earthjustice asserts that RFP is a requirement separate and independent from RACM/RACT and that the EPA's approach undermines Congress' intent for RFP and milestones to serve as enforceable targets that will trigger consequences when RACM/RACT controls are not implemented on a particular schedule.

Earthjustice also states that the Plan's RACM/RACT demonstration cannot support the RFP targets approved by the EPA because it is incomplete, particularly for ammonia. According to Earthjustice, the ammonia RACM/RACT demonstration sets no RACM/RACT requirements and therefore makes it impossible to assess whether the Plan will achieve RFP. Further, Earthjustice says, because the Plan allows ammonia emissions to increase after 2012, it does not provide "annual incremental *reductions*" (emphasis in comment) as required by CAA section 171. Earthjustice states that the EPA must disapprove the RFP demonstration because it has no basis for concluding that the Plan will provide such annual incremental reductions in emissions of the relevant air pollutant as are required for the purpose of ensuring attainment by the applicable date.

Response 13: We disagree with the commenter's assertion that the EPA's approach to RFP in this action is inconsistent with the statutory RFP requirements.

Section 172(c)(2) of the Act requires that plan provisions for all $PM_{2.5}$ nonattainment areas require RFP, which is defined in section 171(1) as such annual incremental reductions in emissions of the relevant air pollutant as are required by part D, title I of the Act or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable date. In the EPA's July 29, 2016 final rule to implement the $PM_{2.5}$ NAAQS, the EPA explained that for areas that cannot demonstrate attainment by the statutory deadline for Moderate areas in CAA section 188(c)(1), the state must demonstrate either generally linear or stepwise emissions reductions toward the full amount of reductions that will be achieved by that deadline, *i.e.,* the amount that reflects implementation of all of the control measures identified as RACM and RACT and additional reasonable measures for the entire period of the applicable attainment plan.[156] The EPA explained that generally linear progress toward this full amount would meet the RFP requirement, while slower progress would require further justification.[157]

As we explained in our proposed rule, the 2012 $PM_{2.5}$ Plan shows that emissions of direct $PM_{2.5}$, NO_X and SO_X will decline from the 2007 base year through 2015 and states that emissions will remain below the levels needed to show "generally linear progress" from 2007 to 2019, the year that the Plan projects to be the earliest practicable attainment date.[158] The Plan also demonstrates that all RACM/RACT and additional reasonable measures for sources of direct $PM_{2.5}$, NO_X, SO_X and ammonia are being implemented as expeditiously as practicable [159] and identifies projected emission levels for each of these pollutants in 2014 and 2017 that reflect full implementation of the State's and District's Moderate area control strategy for the area.[160] In an area that cannot practicably attain the $PM_{2.5}$ NAAQS by the applicable Moderate area attainment date, we believe it is reasonable to find that full implementation of a control strategy that satisfies the Moderate area control requirements (*i.e.,* RACM/RACT and additional reasonable measures) represents reasonable further progress toward attainment.

We also disagree with the commenter's claim that the Plan's RACM/RACT demonstration for ammonia cannot support the RFP targets approved by the EPA because it is incomplete and lacks any RACM/RACT requirements. For the reasons provided above in Response 6 through Response 10, we find the RACM/RACT demonstration in the 2012 $PM_{2.5}$ Plan consistent with the statutory requirement for RACM/RACT in CAA section 189(a)(1)(C).

Finally, we disagree with Earthjustice's claim that the Plan fails to satisfy the RFP requirement because it allows ammonia emissions to increase after 2012 and, therefore, does not provide annual incremental reductions as required by CAA section 171. As the EPA explained in the preamble to the July 29, 2016 final rule to implement the $PM_{2.5}$ NAAQS, states may in certain circumstances develop approvable RFP plans in which emissions of one or more $PM_{2.5}$ precursors subject to control evaluation are not decreasing. The EPA explained that in this scenario:

> . . . The state must demonstrate that the emissions reductions of direct $PM_{2.5}$ combined with the aggregate emissions reductions of $PM_{2.5}$ plan precursors support expeditious attainment of the applicable $PM_{2.5}$ NAAQS. To accomplish this, the EPA expects that a state could use the relative air quality impacts of the different $PM_{2.5}$ plan precursors identified in the attainment modeling to demonstrate that the emissions reductions of direct $PM_{2.5}$ and aggregate $PM_{2.5}$ plan precursors constitute an acceptable RFP plan. For example, the state could demonstrate that even if one or more $PM_{2.5}$ plan precursor is not decreasing, the emissions reductions of direct $PM_{2.5}$ and the remaining $PM_{2.5}$ plan precursors are the dominant factors in reducing ambient $PM_{2.5}$ levels and are therefore adequate to support expeditious attainment. In providing this flexibility, the EPA recognizes that control measures for certain pollutants may be more effective at reducing $PM_{2.5}$ concentrations than others, and that states may be able to implement some measures more quickly than others while still achieving reasonable overall progress toward attainment.[161]

Consistent with these recommendations, the 2012 $PM_{2.5}$ Plan demonstrates that despite the increase in ammonia emissions after 2012, the reductions in emissions of direct $PM_{2.5}$, NO_X and SO_X are the dominant factors in reducing ambient $PM_{2.5}$ levels and are therefore adequate to support expeditious attainment.[162] Because the Plan provides for generally linear reductions in emissions of direct PM$_{2.5}$ and PM$_{2.5}$ precursors in the aggregate, we find that it provides for such annual incremental reductions in emissions of the relevant air pollutant as are required by part D, title I of the Act or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable date.

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[156] EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at pp. 178–179.

[157] *Id.*

[158] 80 FR 1816, 1835 (January 13, 2015) (citing 2012 $PM_{2.5}$ Plan, section 9.3).

[159] As explained in Response 12b, *supra,* we are approving the District's commitment in the 2012 $PM_{2.5}$ Plan to adopt Rule 4905 in 2014 as an additional reasonable measure under CAA section 172(c)(6) because it is a control measure implemented after the RACM implementation deadline (December 14, 2013) but before the Moderate area attainment date (December 31, 2015).

[160] *Id.* at 1835, 1836.

[161] EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at p. 179.

As a result of our December 22, 2015 action reclassifying the SJV area as a Serious nonattainment area for the 2006 PM$_{2.5}$ NAAQS, the area is now subject to Serious area planning requirements under subpart 4 and must reevaluate and strengthen its SIP control strategy as necessary to meet the Serious area requirement for BACM and BACT, among other requirements.[163] The State must also demonstrate attainment as expeditiously as practicable, but no later than December 31, 2019, and provide a revised RFP demonstration, both taking into consideration the implementation of the Serious Area control strategy.[164] Today, we are approving certain elements of the 2012 PM$_{2.5}$ Plan only for the limited purpose of satisfying the statutory control requirements that apply to Moderate areas demonstrating that attainment by the Moderate Area attainment date under subpart 4 is impracticable.

Comment 14: Earthjustice asserts that the EPA does not have authority to defer action on quantitative milestones and RFP contingency measures. Earthjustice notes that the EPA has deemed the District's SIP revision complete and asserts that the EPA is under a mandatory duty as a result to take one of the actions enumerated in CAA section 110(k). Earthjustice contends that disapproval of the quantitative milestones and RFP contingency measures is the only reasonable option. According to Earthjustice, deferring action on these parts effectively waives the statutory consequences for failing to submit a complete plan, including sanctions, and leaves the District with "no actual plan for attaining the PM$_{2.5}$ standards." Earthjustice says that interim milestones and RFP targets will be needed to ensure progress before the District's next attainment plan is adopted.

Response 14: These comments are outside the scope of this action. We did not propose any action concerning quantitative milestones or RFP contingency measures in the Plan and, therefore, are not finalizing any action with respect to these requirements at this time.

For all areas designated nonattainment for the 2006 PM$_{2.5}$ NAAQS effective December 14, 2009, including the SJV area, the EPA has established December 31, 2014 as the starting point for the first 3-year period for quantitative milestones under CAA section 189(c).[165] This is because December 31, 2014, was the due date for states to submit additional SIP elements necessary to satisfy the subpart 4 Moderate area requirements for the 1997 and 2006 PM$_{2.5}$ standards.[166] Establishing December 31, 2014 as the starting point for the first 3-year period under CAA section 189(c) for the 2006 PM$_{2.5}$ NAAQS is in keeping with the EPA's historical approach to quantitative milestone dates (*i.e.,* using the due date for the Moderate area plan submission as the starting point for the first 3-year milestone period). Thus, for the SJV PM$_{2.5}$ Serious nonattainment area, the state must submit quantitative milestones to be achieved by December 31, 2017 (the first milestone date) and every 3 years thereafter until the milestone date that falls within 3 years after the Serious area attainment date.[167]

With respect to RFP contingency measures, we explained in our proposed rule that once the SJV area is reclassified as a Serious area, the State would be obligated to demonstrate that the SIP provides for the implementation of BACM and BACT and for attainment as expeditiously as practicable, and no later than 2019.[168] We also noted that as part of this demonstration, the State would need to revise its RFP demonstration to establish new RFP targets, quantitative milestones, and RFP contingency measures for the 2006 PM$_{2.5}$ NAAQS. As a consequence of our January 20, 2016 final action reclassifying the SJV area as a Serious area for the 2006 PM$_{2.5}$ NAAQS, California is subject to an August 21, 2017 deadline to submit these Serious area plan elements.[169]

Following the State's submission of a Serious area plan to provide for attainment of the 2006 PM$_{2.5}$ NAAQS in the SJV area, the EPA intends to review the submitted plan for compliance with these requirements for quantitative milestones and RFP contingency measures.

E. Comments Regarding Interpollutant Trading Ratios for NNSR

Comment 15: The SJVUAPCD disagrees with the EPA's proposal to disapprove the District's NNSR interpollutant trading (IPT) ratios to offset PM$_{2.5}$ emission increases with NO$_X$ and SO$_X$ emissions reductions. The District asserts that its use of a single IPT ratio for each pollutant based on the average of different calculated ratios across the District is simpler and more equitable than the EPA's suggestion that ratios should either differ across the regions of the SJV or be set based on a maximum calculated value for any point in the SJV. The District believes the EPA's suggested geographically-based ratios would be unfair, since the ratio used for a particular source could depend on which side of the road it is located on.

The SJVUAPCD further asserts that the District's reliance on the use of a basin-wide average for each pollutant is consistent with the EPA's NNSR regulations at 40 CFR part 51, Appendix S, as well as prior EPA approvals of NNSR programs that mitigate emission increases across an air basin. The District also states that it models local impacts of increased PM$_{2.5}$ emissions for every facility subject to NNSR and will not issue a permit to a facility if the modeled impacts indicate a significant health risk or a significant increase in PM$_{2.5}$ emissions. The SJVUAPCD concludes that its NNSR modeling analysis and proposed IPT ratios prevent localized impacts and appropriately offset regional impacts, and that the EPA should therefore approve the ratios.

Response 15: We disagree with the District's assertion that the EPA should approve the NNSR IPT ratios in the 2012 PM$_{2.5}$ Plan. Our primary concern regarding the District's approach to interpollutant trading for NSR purposes is that the Plan provided only a ratio calculation, without a rationale to support the use of this ratio for NNSR purposes. Under section IV.G.5 of 40 CFR part 51, Appendix S, interpollutant trades to meet NNSR offset requirements for emissions of direct $PM_{2.5}$ or $PM_{2.5}$ precursors may be allowed if such offsets comply with an interprecursor trading hierarchy and ratio approved by the Administrator. As stated in our proposal, the EPA issued a 2011 guidance memorandum on interpollutant trading stating that "any ratio involving $PM_{2.5}$ precursors submitted to the EPA for approval for use in a state's interpollutant offset program for $PM_{2.5}$ nonattainment areas must be accompanied by a technical demonstration that shows the net air quality benefits of such ratio for the $PM_{2.5}$ nonattainment area in which it will be applied."[170] Therefore, a $PM_{2.5}$ NNSR SIP submittal containing interpollutant trading ratios for use in NNSR offsetting must describe a method for calculating ratios and provide a rationale demonstrating that the method is consistent with the purpose of NNSR offsets.

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[162] 80 FR 1816, 1835–1836 (January 13, 2015).

[163] 81 FR 2993 (January 20, 2016) (final rule) and 81 FR 42263 (June 29, 2016) (correcting amendment).

[164] *Id.*

[165] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at 40 CFR 51.1013(a)(4). Although this regulatory text is not yet effective, it reflects the EPA's interpretation of the statutory requirements.

[166] EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at p. 203 (referencing 79 FR 31566 (June 2, 2014) (final rule establishing subpart 4 moderate area classifications and deadline for related SIP submissions)); *see also* 80 FR 1816, 1835 (January 13, 2015).

[167] *See* EPA, Final Rule, "Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements," July 29, 2016 (pre-publication notice) at 40 CFR 51.1013(a)(4). Although this regulatory text is not yet effective, it reflects the EPA's interpretation of the statutory requirements.

[168] 80 FR 1816, 1837 (January 13, 2015).

[169] 81 FR 2993, 3000 (January 20, 2016) and 40 CFR 52.247(e).

The EPA disagrees with the District's claim that the use of a single trading ratio, even the maximum ratio over an area, is necessarily more equitable or less complex than using multiple ratios. While the use of a single interpollutant trading ratio for all locations in a nonattainment area may be simpler than separate ratios for different geographic zones, the District has provided no rationale concerning the net air quality benefits of such an approach. The impact of emissions of a given pollutant varies by the chemical environment the emissions occur in, and that chemical environment varies by location. The ratio of impacts between emissions of NO_X and SO_X precursors will also necessarily vary by geographic location. The importance of that impact for total concentration is another consideration; emissions from a remote, relatively clean area used to offset emissions in a highly polluted area may not meet the requirement in Condition 3 of 40 CFR part 51, Appendix S, section IV.A, which states that offsets from existing sources in the area of the proposed source are required such that there will be reasonable progress toward attainment of the applicable NAAQS. The use of a ratio that is an average over a broad geographic area, or any ratio less than the maximum ratio for such an area, could allow for a new source whose location-specific modeling gives the maximum ratio to obtain a permit without offsetting its full impact and, thus, potentially interfere with progress toward attainment.

The District suggests that the use of the maximum ratio poses an equity problem for a source whose location-specific ratio is lower, as such a source would have to offset more than it should. However, the use of an average ratio across the entire nonattainment area poses a different equity problem: A source whose location-specific ratio is the maximum would be offsetting less than it should while other sources would have to offset more. Use of different ratios tailored to specific geographic zones would be one way to help address these issues. Although the District correctly notes that a source located to one side of a zone boundary may have a different ratio than one located just to the other side of the boundary, creating potential inequities, we believe such an approach is generally more appropriate and equitable as sources in each zone would offset approximately their fair share. In any case, the EPA will review each technical demonstration accompanying an NNSR SIP submission to determine whether the state's requested interpollutant trading ratio(s) will achieve a net air quality benefit in the $PM_{2.5}$ nonattainment area.

Comment 16: The SJVUAPCD disagrees with the EPA's proposal to disapprove the District's interpollutant trading ratio sensitivity calculation based on a 50 percent reduction in stationary source emissions. The District comments that the EPA has provided only limited guidance on the development of interpollutant trading ratios and has failed to propose a mechanism to determine the sensitivity of $PM_{2.5}$ formation to NO_X and SO_X emission decreases for NNSR, even though, according to the District, federal law requires the EPA to do so. The District asserts that its method is consistent with the EPA's existing guidance on NNSR IPT ratios and with state techniques that the EPA has approved for attainment demonstration purposes. The District contends that the EPA's disapproval of its approach creates new standards not reflected in previous guidance, and that the EPA should establish new standards only through the proper regulatory approval process. The District states that the EPA should therefore approve its 50 percent reduction sensitivity approach.

Response 16: Although it may be reasonable to use modeling of 50 percent reductions in calculating interpollutant trading ratios,[171] consistent with the provisions of 40 CFR part 51, Appendix S and EPA guidance, the state must provide a rationale for the reduction used and demonstrate its appropriateness for NSR offsetting purposes. As we stated in our proposed rule, the Plan provides no rationale for the appropriateness of a 50 percent reduction. Generally, the emission reductions model should have a direct connection to the emission reductions expected in IPT trades for NSR offsetting.

Comment 17: The District disagrees with the EPA's general comment that the Plan fails to provide an overall rationale for the District's methodology that is grounded in the statutory purpose of NSR offsets, and also with the EPA's specific concern that the 2012 $PM_{2.5}$ Plan does not show that its offsets provide a "net air quality benefit in the affected area," as required by 40 CFR part 51, Appendix S, section IV.A. The District asserts that Appendix H of the Plan demonstrates that the Plan's interpollutant trading ratios are consistent with the federal NNSR requirements and that the use of credits would not interfere with attainment efforts. The District states that the proposed trading ratios substitute only one precursor pollutant to the current offsetting requirements that the EPA has already found "to comply with the CAA and EPA's NSR implementation regulations," and that this substitution uses a predetermined ratio demonstrated to be equal in ability to offset $PM_{2.5}$. For this reason, the District argues that the ratios have already been demonstrated to provide an air quality benefit to the area and should be approved.

Response 17: The EPA disagrees with the District's claim that the Plan demonstrates that its proposed interpollutant offsets would not interfere with attainment efforts, and that its ratio represents equivalent $PM_{2.5}$ offsetting impacts. As we explained above in Response 15 concerning location-specific ratios, depending on the locations of the new or modified sources and the offsetting sources, offsets based on interpollutant trades could interfere with progress toward attainment of the $PM_{2.5}$ NAAQS. The District used modeling of emission reductions occurring over a large geographic area and calculated ratios of the effects at multiple monitor locations, without providing a rationale for the procedure used. The modeling reflects the average response of geographically distributed emission reductions but does not show the effect of any particular offset for a new source, and it is unclear how it is related to the aggregate effect of many such trades. Because the 2012 PM$_{2.5}$ Plan does not address the locations of either the PM$_{2.5}$ precursor emission increases and offsets or the ambient PM$_{2.5}$ effects, we find the technical analyses in the Plan insufficient to demonstrate that the District's proposed offset ratio will assure reasonable progress toward attainment of the PM$_{2.5}$ NAAQS in the SJV.

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[170] Memorandum dated July 21, 2011, from Gina McCarthy, Assistant Administrator, to Regional Air Division Directors, Regions 1–10, Subject: Revised Policy to Address Reconsideration of Interpollutant Trading Provisions for Fine Particles ($PM_{2.5}$) ("IPT memo").

[171] We note, however, that such a level of reduction does not match the scale of reductions involved in a typical NNSR offsetting transaction.

F. Comments on Motor Vehicle Emissions Budgets

Comment 18: Earthjustice agrees with the EPA's proposal to disapprove the interpollutant trading ratios for NSR but argues that the EPA should also disapprove the District's 8:1 ratio for offsetting mobile source emission increases of PM$_{2.5}$ for conformity purposes. Earthjustice claims that the EPA did not evaluate the methodology supporting this ratio and instead approved it on the basis that it was more stringent than regional modeling determinations. According to Earthjustice, given the EPA concluded that the regional modeling was arbitrary and lacked any rationale for its methodology, the mere fact that the conformity ratios are "more stringent" does not provide the EPA with any rational basis for approving an 8:1 ratio for conformity purposes.

Response 18: The EPA disagrees with Earthjustice's claim that the 8:1 NO$_{X}$:direct PM$_{2.5}$ ratio for transportation conformity has no rational basis. As an initial matter, we note that the EPA did not state that the regional modeling was arbitrary, but rather that the Plan had not provided a rationale for its particular approach to using modeled sensitivity ratios to derive IPT ratios for NSR offsetting purposes.[172] The EPA made these statements in the context of NNSR permitting requirements, not trading mechanisms for transportation conformity purposes.

The District's methodology for estimating the IPT ratio for conformity purposes is essentially an update (based on newer modeling) of the approach that the EPA previously approved for the 2008 PM$_{2.5}$ Plan for the 1997 PM$_{2.5}$ NAAQS in the SJV.[173] The District's approach in the 2008 PM$_{2.5}$ Plan was to model the ambient PM$_{2.5}$ effect of areawide NO$_{X}$ emissions reductions and of areawide direct PM$_{2.5}$ reductions, and to express the ratio of these modeled sensitivities as an interpollutant trading ratio. Variable factors in this method included the extent of the area over which emission reductions were applied and the location(s) at which the resulting ambient PM$_{2.5}$ effect was evaluated. As part of the EPA's November 2011 action partially approving the 2008 PM$_{2.5}$ Plan for the 1997 PM$_{2.5}$ NAAQS in the SJV, the EPA stated that this methodology "is adequate for purposes of assessing the effect of area-wide emissions changes, such as are used in RFP, contingency measures, and conformity budgets."[174] In the TSD supporting that action, we stated that "[t]he method modeled 'across the board' emission changes over the entire modeling domain; emissions considered in transportation conformity are also domain-wide."[175]

As part of our proposed action on the 2012 PM$_{2.5}$ Plan, we stated that the areawide methodology used in the 2008 PM$_{2.5}$ Plan gave a range of IPT ratios from 2.8 to 4.7, depending on the ambient location chosen.[176] Using the same method would entail using the IPT ratio evaluated at the California Street, Bakersfield design value site, 4:3. The 8:1 ratio used in the Plan is larger than both the Bakersfield ratio and any ratio using variants of the previously-approved approach, and is thus a more stringent (and conservatively high) trading mechanism to use for estimating the NO$_{X}$ reductions needed to offset PM$_{2.5}$ increases.[177] We are approving the 8:1 trading ratio for transportation conformity purposes because it is significantly more stringent than any of the other ratios calculated in the Plan for different locations in the SJV, all of which were calculated using a methodology that the EPA previously approved for transportation conformity purposes in the SJV.

Comment 19: Earthjustice comments that the EPA's conformity regulations require MVEB to be consistent with the requirements for RFP. Earthjustice argues that because the RFP demonstration is not approvable, the EPA also should not approve the MVEBs.

Response 19: We disagree with Earthjustice's claim that the EPA should disapprove the MVEBs in the Plan.

As we explained above in Response 13, we are approving the RFP demonstration in the 2012 PM$_{2.5}$ Plan based on our conclusion that it provides for generally linear reductions in emissions of direct PM$_{2.5}$ and PM$_{2.5}$ precursors in the aggregate and, therefore, provides for such annual incremental reductions in emissions of the relevant air pollutant as are required by part D, title I of the Act or may reasonably be required by the Administrator for the purpose of ensuring attainment of the 2006 PM$_{2.5}$ NAAQS by the applicable attainment date.

The 2012 PM$_{2.5}$ Plan contains 2014 and 2017 MVEBs for emissions of direct PM$_{2.5}$ and NO$_{X}$. We proposed to approve these budgets based on a conclusion that they are consistent with applicable requirements for RFP, are clearly identified and precisely quantified, and meet all other applicable statutory and regulatory requirements including the adequacy criteria in 40 CFR 93.118(e)(4).[178] Additionally, in accordance with 40 CFR 93.102(b)(2)(v), we proposed to find that on-road emissions of VOCs, SO$_{2}$ and ammonia are not significant contributors to the PM$_{2.5}$ nonattainment problem in the SJV area, and accordingly, that transportation conformity requirements do not apply for these pollutants in this area.[179] In April 2016, the EPA found the direct PM$_{2.5}$ and NO$_{X}$ MVEBs in the Plan, as submitted December 29, 2014, adequate for transportation conformity purposes.[180] On November 13, 2015, the State submitted revised direct PM$_{2.5}$ and NO$_{X}$ budgets based on EMFAC2014 for the 2006 PM$_{2.5}$ NAAQS. The EPA proposed to approve these revised budgets based on our conclusion that the 2012 PM$_{2.5}$ Plan continues to meet applicable requirements for RFP in 2017 when the EMFAC2011-based budgets are replaced with the new EMFAC2014-based budgets and that these budgets are clearly identified, precisely quantified, and meet all of the other criteria in 40 CFR 93.118(e)(4).[181]

The commenter has not identified any information that compels us to reconsider our conclusion that the MVEBs in the 2012 $PM_{2.5}$ Plan are consistent with applicable requirements for reasonable further progress. Therefore, we are approving the 2017 MVEBs for direct $PM_{2.5}$ and NO_X, as submitted November 13, 2015.[182]

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[172] 80 FR 1816, 1838 (January 13, 2015).

[173] *See* 80 FR 1816, 1841 (January 13, 2015) (noting the EPA's prior approval of MVEBs for the 1997 annual and 24-hour PM$_{2.5}$ standards in the 2008 PM$_{2.5}$ Plan at 76 FR 69896, November 9, 2011).

[174] 76 FR 69896, 69919 (November 9, 2011).

[175] EPA, Region 9, Air Division, "Technical Support Document and Responses to Comments, Final Rule on the San Joaquin Valley 2008 PM$_{2.5}$ State Implementation Plan," September 30, 2011, at pp. 46 and 165.

[176] The maximum ratio for the 1st Street location in Fresno was actually 5:2, based on emission reduction sensitivities for NO$_{X}$ and for direct PM in the State's Weight of Evidence Analysis, Appendix G to the 2012 PM$_{2.5}$ Plan, Table 7, p. G–65.

[177] The Bakersfield ratio is based on values in "Table 7. Modeled PM$_{2.5}$ air quality benefit per ton of valley wide precursor emission reductions", 2012 PM$_{2.5}$ Plan, Appendix G, p. 65.

[178] 80 FR 1816, 1840 (January 13, 2015).

[179] *Id.*

[180] Letter dated April 1, 2016, from Deborah Jordan, Director, Air Division, EPA, to Richard W. Corey, Executive Officer, California Air Resources Board, and 81 FR 22194 (April 15, 2016).

[181] 81 FR 31212, 31218 (May 18, 2016).

We note that, because the provisions of 40 CFR part 93, subpart A, apply only with respect to emissions of NO_X and direct $PM_{2.5}$ for purposes of the 2006 $PM_{2.5}$ NAAQS in the SJV area, the commenter's arguments about ammonia emissions are not germane to our action on these MVEBs.

G. Other Comments

Comment 20: Earthjustice asserts that the EPA has no basis for deferring action on the NSR component of the Plan and that deferral will put the EPA in violation of the statutory deadlines under CAA section 110(k)(2). Earthjustice states that the District's NSR program does not meet all subpart 4 requirements because it does not regulate ammonia, which according to Earthjustice is required under CAA section 189(e).

Response 20: These comments are outside the scope of this action. We did not propose any action on the portions of the 2014 Supplement that address NNSR requirements for $PM_{2.5}$ in the SJV and, therefore, are not finalizing any action with respect to these Plan elements at this time. The EPA intends to act on these components of the Plan through a separate rulemaking.

We note that as a consequence of the EPA's January 20, 2016 final action reclassifying the SJV area as a Serious nonattainment area for the 2006 $PM_{2.5}$ NAAQS, California is subject to a February 21, 2017 deadline to submit NNSR rule revisions for the SJV that satisfy the requirements of sections 189(b)(3) and 189(e) and all other applicable requirements of the CAA for implementation of the 2006 $PM_{2.5}$ NAAQS.[183] These SIP revisions must appropriately address the NNSR requirements for direct $PM_{2.5}$ and all $PM_{2.5}$ precursors, including ammonia.

III. Final Action

The EPA is taking final action to approve elements of the following SIP revisions submitted by California to address Clean Air Act requirements for implementation of the 2006 $PM_{2.5}$ NAAQS in the SJV: The 2012 $PM_{2.5}$ Plan, submitted March 4, 2013; the 2014 Supplement, submitted November 6, 2014; and the motor vehicle emissions budgets for direct $PM_{2.5}$ and NO_X, as submitted November 13, 2015.

Specifically, under CAA section 110(k)(3), the EPA is proposing to approve the following elements of the 2012 $PM_{2.5}$ Plan and 2014 Supplement:

1. The 2007 base year emissions inventories as meeting the requirements of CAA section 172(c)(3);
2. the demonstration that attainment by the Moderate area attainment date of December 31, 2015 is impracticable as meeting the requirements of CAA section 189(a)(1)(B)(ii);
3. the reasonably available control measures/reasonably available control technology demonstration as meeting the requirements of CAA sections 172(c)(1) and 189(a)(1)(C);
4. the reasonable further progress demonstration as meeting the requirements of CAA section 172(c)(2); and
5. SJVUAPCD's commitments to adopt and implement specific rules and measures by the dates specified in Chapter 5 of the 2012 $PM_{2.5}$ Plan to achieve the emissions reductions shown therein, and to submit these rules and measures to CARB within 30 days of adoption for transmittal to the EPA as a revision to the SIP, or if the total emission reductions from the adopted rules are less than those committed to in the Plan, to adopt, submit, and implement substitute rules that will achieve equivalent reductions in emissions of direct $PM_{2.5}$ or $PM_{2.5}$ precursors in the same adoption and implementation timeframes or in the timeframes needed to meet CAA milestones, as stated on p. 4 of SJVUAPCD Governing Board Resolution 12–12–19, dated December 20, 2012, "In the Matter of Adopting the San Joaquin Valley Unified Air Pollution Control District *2012 $PM_{2.5}$ Plan.*"

In addition, the EPA is approving the 2017 NO_X and $PM_{2.5}$ motor vehicle emissions budgets submitted November 13, 2015,[184] as shown in Table 1 above, because they are derived from an approvable RFP demonstration and meet the applicable requirements of CAA section 176(c) and 40 CFR part 93, subpart A. We are also approving, in accordance with 40 CFR 93.124, the trading mechanism described on p. C–32 in Appendix C of the 2012 $PM_{2.5}$ Plan as an enforceable component of the transportation conformity program for the 2006 $PM_{2.5}$ NAAQS in the SJV, with the condition that the trades are limited to substituting excess reductions in NO_X for increases in $PM_{2.5}$. The budgets that the EPA is approving herein relate to the 2006 $PM_{2.5}$ NAAQS only, and our approval of them does not affect the status of the previously-approved MVEBs for the 1997 $PM_{2.5}$ NAAQS and related trading mechanism, which remain in effect for that $PM_{2.5}$ NAAQS.

The EPA is disapproving the $PM_{2.5}$ interpollutant trading ratios provided in Appendix H of the 2012 $PM_{2.5}$ Plan for NNSR permitting purposes. Under section 179(a) of the CAA, final disapproval of a SIP submittal that addresses a requirement of part D, title I of the Act or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP Call) starts a sanctions clock. The NNSR interpollutant trading ratios provided in the 2012 $PM_{2.5}$ Plan were not submitted to meet either of these requirements. Therefore, our final action to disapprove this component of the Plan does not trigger a sanctions clock. Disapproval of a SIP element also triggers the requirement under CAA section 110(c) for the EPA to promulgate a Federal Implementation Plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiency, and the Administrator approves the plan or plan revision, before the Administrator promulgates such FIP. Disapproval of these NNSR interpollutant trading ratios, however, does not create any deficiency in the Plan, and therefore does not trigger the obligation on the EPA to promulgate a FIP under section 110(c).

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

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[182] Although the 2012 $PM_{2.5}$ Plan contained MVEBs for both 2014 and 2017, MVEBs for 2014 are no longer relevant for conformity analyses since that year has passed.

[183] 81 FR 2993, 3000 (January 20, 2016) and 40 CFR 52.245(e).

[184] See letter dated November 13, 2015, from Richard W. Corey, Executive Officer, CARB to Jared Blumenfeld, Regional Administrator, EPA Region 9, with enclosures.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 31, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 16, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region 9.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(476)(ii)(A)(*2*), (c)(478), and (c)(479) to read as follows:

§ 52.220 Identification of plan—in part.

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(c) * * *

(476) * * *

(ii) * * *

(A) * * *

(*2*) Attachment A to Resolution 15–50, "Updates to the Transportation Conformity Budgets for the San Joaquin Valley 2007 PM_{10}, 2007 Ozone and 2012 $PM_{2.5}$ SIPs," Table A–2 (Updated Transportation Conformity Budgets for the 2012 $PM_{2.5}$ Plan (Tons per winter day).

* * * * *

(478) The following plan was submitted on March 4, 2013, by the Governor's Designee.

(i) [Reserved]

(ii) Additional materials.

(A) San Joaquin Valley Unified Air Pollution Control District.

(*1*) "2012 $PM_{2.5}$ Plan" (dated December 20, 2012), adopted December 20, 2012, except for the motor vehicle emission budgets used for transportation conformity purposes.

(*2*) SJVUAPCD Governing Board Resolution No. 12–12–19, dated December 20, 2012, "In the Matter of Adopting the San Joaquin Valley Unified Air Pollution Control District *2012 $PM_{2.5}$ Plan.*"

(*3*) SJVUAPCD's commitments to adopt and implement specific rules and measures by the dates specified in Chapter 5 of the 2012 $PM_{2.5}$ Plan to achieve the emissions reductions shown therein, and to submit these rules and measures to CARB within 30 days of adoption for transmittal to EPA as a revision to the SIP, or if the total emission reductions from the adopted rules are less than those committed to in the Plan, to adopt, submit, and implement substitute rules that will achieve equivalent reductions in emissions of direct $PM_{2.5}$ or $PM_{2.5}$ precursors in the same adoption and implementation timeframes or in the timeframes needed to meet CAA milestones, as stated on p. 4 of SJVUAPCD Governing Board Resolution 12–12–19, dated December 20, 2012.

(B) California Air Resources Board.

(*1*) CARB Resolution 13–2, dated January 24, 2013, "San Joaquin Valley $PM_{2.5}$ State Implementation Plan."

(479) The following plan was submitted on November 6, 2014, by the Governor's Designee.

(i) [Reserved]

(ii) Additional materials.

(A) San Joaquin Valley Unified Air Pollution Control District.

(*1*) "Supplemental Document, Clean Air Act Subpart 4: The 2012 $PM_{2.5}$ Plan for the 2006 $PM_{2.5}$ Standard and District Rule 2201 (New and Modified Stationary Source Review)" (dated September 18, 2014), adopted September 18, 2014.

(*2*) SJVUAPCD Governing Board Resolution No. 14–09–01, dated September 18, 2014, "In the Matter of: Authorizing Submittal of "Supplemental Document for the 2012 $PM_{2.5}$ Plan" to EPA."

(B) California Air Resources Board.

(*1*) CARB Resolution 14–37, dated October 24, 2014, "Supplemental Document for the San Joaquin Valley 24-Hour $PM_{2.5}$ State Implementation Plan."

[FR Doc. 2016–20413 Filed 8–30–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1647–CN]

RIN 0938–AS78

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects typographical errors in the final rule that appeared in the August 5, 2016 **Federal Register** entitled, "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017".

DATES: The final rule published August 5, 2016 (81 FR 52056 through 52141) is corrected as of August 30, 2016.

FOR FURTHER INFORMATION CONTACT: Christine Grose, (410) 786- 1362.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2016–18196 (81 FR 52056 through 52141), the final rule entitled, "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017" (hereinafter referred as the FY 2017 IRF PPS final rule), there were typographical errors that are identified and corrected in this correcting document. The correction is applicable as of August 30, 2016.

II. Summary of Errors in the Preamble

On page 52118 of the FY 2017 IRF PPS final rule, we inadvertently included a reference to Table 10 instead of Table 18.

On page 52118 of the FY 2017 IRF PPS final rule, we inadvertently included a reference to Table 10 instead of Table 11.

On page 52118 of the FY 2017 IRF PPS final rule, we inadvertently included a reference to Table 10 instead of Table 16.

On page 52118 of the FY 2017 IRF PPS final rule, we inadvertently included a reference to Table 10 instead of Table 17.

On page 52118 of the FY 2017 IRF PPS final rule, in the footnote to Table 10, we inadvertently included a reference to Table 10 instead of Table 17.

On page 52118 of the FY 2017 IRF PPS final rule, in the footnote to Table 10, we inadvertently included a reference to Table 10 instead of Table 16.

On page 52119 of the FY 2017 IRF PPS final rule, in the footnote to Table 11, we inadvertently included a reference to Table 11 instead of Table 10.

On page 52119 of the FY 2017 IRF PPS final rule, in the footnote to Table 13, we inadvertently included a reference to Table 12 instead of Table 10.

On page 52120 of the FY 2017 IRF PPS final rule, in the footnote to Table 14, in two instances, we inadvertently included a reference to Table 14 instead of Table 10.

On page 52120 of the FY 2017 IRF PPS final rule, in the footnote to Table 15, in two instances, we inadvertently included a reference to Table 15 instead of Table 10.

On page 52121 of the FY 2017 IRF PPS final rule, in the footnote to Table 16, we inadvertently included a reference to Table 16 instead of Table 10.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** and provide a period for public comment before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment and delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act, as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest; and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects typographical errors in the preamble of the FY 2017 IRF PPS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were adopted subject to notice and comment procedures in the FY 2017 IRF PPS final rule. As a result, the correction made through this correcting document is intended to resolve inadvertent typographical errors.

Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the FY 2017 IRF PPS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects the our policies as of the date they take effect and are applicable. Further, such procedures would be unnecessary, because we are not making any substantive revision to the final rule, but rather, we are simply correcting the **Federal Register** document to reflect the correct table references in the footnotes. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

IV. Correction of Errors in the Preamble

In FR Doc. 2016–18196 (81 FR 52056), published August 5, 2016, make the following corrections:

1. On page 52118,

a. In the second column, in the second full paragraph, line 11, the reference "Table 10" is corrected to read "Table 18".

b. In the third column, in the first partial paragraph, line 2, the reference "Table 10" is corrected to read "Table 11".

c. In the third column, in the first partial paragraph, line 30, the reference "Table 10" is corrected to read "Table 16".

d. In the third column, in the first partial paragraph, line 37, the reference "Table 10" is corrected to read "Table 17".

e. In the footnote to Table 10, the phrase "*We refer readers to Table 10" is corrected to read "*We refer readers to Table 17".

f. In the footnote to Table 10, the phrase " – We refer readers to Table 10" is corrected to read " – We refer readers to Table 16".

2. On page 52119,

a. In the footnote to Table 11, the phrase "*We refer readers to the Table 11" is corrected to read "*We refer readers to the Table 10".

b. In the footnote to Table 13, the phrase "*We refer readers to the Table 12" is corrected to read "*We refer readers to the Table 10".

3. On page 52120,

a. In the footnote to Table 14, the phrase "*We refer readers to the Table 14" is corrected to read "*We refer readers to the Table 10".

b. In the footnote to Table 14, the phrase "**As is illustrated in Table 14" is corrected to read "**As is illustrated in Table 10".

c. In the footnote to Table 15, the phrase "*We refer readers to the Table 15" is corrected to read "*We refer readers to the Table 10".

d. In the footnote to Table 15, the phrase "***As is illustrated in Table 15" is corrected to read "***As is illustrated in Table 10".

4. On page 52121, in the footnote to Table 16, the phrase "**As illustrated in Table 16" is corrected to read "**As illustrated in Table 10".

Dated: August 25, 2016.

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–20897 Filed 8–30–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3100, 3110, and 3120

[16X.LLWO310000.L13100000.PP0000]

RIN 1004–AE48

BLM Internet-Based Auctions

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This procedural rule amends certain provisions of the oil and gas regulations administered by the Bureau of Land Management (BLM) to recognize that the BLM is authorized to use either oral or internet-based auction procedures to conduct oil and gas lease sales under the Mineral Leasing Act of 1920, as amended (MLA). The changes made by this rule update the BLM's regulations to be consistent with the National Defense Authorization Act for Fiscal Year (FY) 2015 (NDAA), which specifically granted the BLM the authority to use internet-based bidding for its competitive oil and gas lease sales.

DATES: This rule is effective on August 31, 2016.

FOR FURTHER INFORMATION CONTACT: For questions on technical issues, contact Jully McQuilliams, Senior Mineral Leasing Specialist, by telephone at 202–912–7156, or by email to *jmcquilliams@blm.gov.* For regulatory questions, contact Jennifer Noe, Division of Regulatory Affairs, by telephone at 202–912–7442, or by email to *jnoe@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 to contact the above individuals during normal business hours. FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background

This rule makes minor amendments to the BLM regulations governing onshore oil and gas lease sales to make them consistent with existing statutory authority that allows the BLM to use either oral or internet-based auction procedures.

The MLA authorizes the Secretary of the Interior to lease federally owned deposits of oil and gas and the lands containing those deposits in the manner provided for in the Act. 30 U.S.C. 181–287. The Secretary has delegated responsibility for implementing that authority to the BLM. Prior to 2015, the BLM was authorized to conduct oil and gas lease sales using only oral auction methods. *See* 30 U.S.C. 226(b)(1) ("Lease sales shall be conducted by oral bidding."). As a result, the BLM's implementing regulations governing lease sales in 43 CFR parts 3100, 3110, and 3120, reference only oral auctions or oral bidding. *See e.g.,* 43 CFR 3120.1–2, 3120.5–1. Under these regulations, parties interested in obtaining a Federal oil or gas lease were required to travel to the physical location of a BLM auction (normally the BLM State Office where the parcels being offered were located) in order to participate in person in the oral auction for the parcels being offered. Generally speaking, those sales were conducted by a BLM-contracted auctioneer who facilitated the auction in an escalating bid sequential manner. The lease sale would start with the auctioneer stating the minimum bid. Interested bidders would increase their bids until the highest bidder for each parcel prevailed and was ultimately awarded the parcel. *See* 30 U.S.C. 226(b)(1)(A); 43 CFR 3120.5–3(b).

Recognizing the costs associated with holding in-person oil and gas lease sales and the opportunities for increased efficiency provided by an internet-based system, Congress, in 2008, directed the Secretary of the Interior, through the BLM, to conduct an oil and gas leasing internet pilot program. Consolidated Appropriations Act, 2008, Public Law 110–161, Sec. 117, 121 Stat. 2120 (2007). Accordingly, the BLM conducted an internet-based auction pilot in 2009, offering parcels located on BLM-managed lands in Colorado to test the feasibility of internet-based lease sales. The purpose of the pilot was to evaluate the potential costs and benefits to the Federal Government and lease sale participants from using such a system. For this pilot, the BLM relied on a system that had been developed by a private entity.

As outlined in a subsequent report to Congress submitted in February 2012, which presented the results of the 2009 internet-based auction pilot, the BLM found that transitioning to internet-based lease sales would have immediate cost savings and other benefits. Report to Congress, Results of the Internet Oil and Gas Auction Pilot and Recommendation on How to Implement the Program in Fiscal Year 2011 (Dep't of the Interior, Feb. 21, 2012) (Internet Leasing Report). The BLM prepared the report in response to a congressional request. *See* Senate Report 111–38, Department of the Interior, Environment, and Related Agencies Appropriations Bill, 2010 (July 7, 2009). Almost double the number of bidders participated in the internet-based pilot sale as compared to the number that typically participate at an in-person lease sale hosted by the BLM Colorado State Office. In the Internet Leasing Report, the BLM estimated that greater competition among bidders has the potential to increase competitive bonuses by about one percent (approximately $2 million per year in aggregate), (Internet Leasing Report). However, it should be noted that, in addition to the number of bidders, bonus bids are also affected by broader market conditions, and therefore the transition to internet-based leasing could have an even larger impact on auction proceeds. In addition to increased revenues, a shift to internet-based sales would also help reduce the BLM's administrative costs associated with holding a lease sale, and reduce the risk of weather-related or other logistical disruptions in lease sales.

As a result of this auction pilot, the Secretary recommended in his report that Congress amend the MLA to allow the BLM maximum discretion to use either in-person or internet-based procedures to conduct competitive lease sales for BLM-managed onshore oil and gas resources. *Id.* Notably, since the 2009 BLM internet-based auction pilot, many state governments' oil and gas lease sales have moved entirely to online sales, including states with significant oil and gas resources, such as Colorado, North Dakota, Texas, Utah, and Wyoming.

Consistent with the Secretary's recommendations, in the NDAA, Congress amended the MLA at 30 U.S.C. 226(b)(1) to authorize the Secretary of the Interior to "conduct onshore lease sales through Internet-based bidding methods." *See* Public Law 113–291, Sec. 3022(a), 128 Stat. 3762 (2014). The NDAA adds a new paragraph to section 226(b)(1), which provides: "In order to diversify and expand the Nation's onshore leasing program to ensure the best return to the Federal taxpayer, reduce fraud, and secure the leasing process, the Secretary may conduct onshore lease sales through Internet-based bidding methods. Each individual Internet-based lease sale shall conclude within 7 days."

The NDAA does not modify parcel selection, bidder eligibility, auction style, or payment requirements, which will continue to apply regardless of the method selected by the BLM to conduct a particular oil and gas lease sale. The BLM will also continue to award leases to the highest responsible qualified bidder at its competitive auctions, pursuant to the MLA. Consistent with existing regulations at 43 CFR subpart 3110, if a parcel offered for sale does not sell at a competitive auction, it will be available on a noncompetitive basis in the BLM State Offices with jurisdiction over the areas where the parcels are located for the period of time set forth in the regulations.

II. Explanation of Amendments

The BLM has determined that this procedural rule is necessary because the BLM's existing regulations refer only to oral auction or oral bidding, even though the BLM is statutorily authorized to use either oral or internet-based auction procedures to conduct its oil and gas lease sales. To implement the new authority provided by the NDAA, this rule amends 43 CFR subparts 3100, 3110, and 3120 to add the phrase "or internet-based" after every reference to "oral" auctions or bidding. Specific changes are made to the following provisions: 43 CFR 3103.3–2, 3110.1, 3110.2, 3120.1–2, 3120.3–7, 3120.5–1, 3120.5–2, 3120.5–3, and 3120.6.

This rule does not make any other changes to the regulations in 43 CFR chapter II. It does not change the parcel selection, bidder eligibility, auction style, or payment requirements for the BLM's competitive oil and gas lease sales. This rule merely makes minor technical amendments that give the BLM the option to conduct lease sales either in person or over the internet consistent with applicable statutory authority.

III. Procedural Matters

A. Administrative Procedure Act

As explained in the Background Section of this Preamble, this rule makes minor, non-substantive, technical amendments to the BLM's rules governing oil and gas lease sales. These changes involve agency organization, procedure or practice, and do not create rights or impose obligations on members of the public. As a result, under section 553(b)(3)(A) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(A), this rule may be published without notice and comment procedures. Because the rule relates solely to agency procedure and practice and merely restates the terms of the statute it implements, it is not substantive, and therefore is also not subject to the 30-day delayed effective date for substantive rules under section 553(d) of the APA. 5 U.S.C. 553(d). This rule is therefore effective immediately upon publication in the **Federal Register**.

The U.S. Court of Appeals for the District of Columbia has emphasized that the "critical feature" of a rule that satisfies the so-called procedural exception to the APA's notice-and-comment requirements is that the rule "covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." *James V. Hurson Assoc.* v. *Glickman,* 229 F.3d 277, 280 (D.C. Cir. 2000) (*quoting JEM Broad Co.* v. *FCC,* 22 F.3d 320, 326 (D.C. Cir. 1994)). The court held in *Hurson* that a U.S. Department of Agriculture rule eliminating face-to-face meetings to approve food labels was within the APA's procedural exception because the rule did not alter the substantive standards by which the agency would approve or deny proposed labels; it simply changed the procedures the agency would follow in applying those standards. Similarly, this BLM rule adding a reference to internet-based auctions merely alters the manner in which parties may present themselves to the BLM; nothing in this rule alters either the substantive criteria by which a party is eligible to participate in a BLM oil and gas lease sale or the requirements for obtaining a Federal oil and gas lease. Therefore, the rule fits squarely within the procedural rule exemption. *See also Nat'l Whistleblower Ctr.* v. *Nuclear Regulatory Comm'n,* 208 F.3d 256, 262 (D.C. Cir. 2000), *cert. denied,* 531 U.S. 1070 (2001).

Moreover, when a rule merely restates the statute it implements, APA notice-and-comment procedures are unnecessary. *See Komjathy* v. *Nat'l Transp. Safety Bd.,* 832 F.2d 1294 (D.C. Cir. 1987), *cert. denied,* 486 U.S. 1057 (1988). Here, the BLM's amendments to 43 CFR parts 3100, 3110 and 3120 do no more than restate the relevant language of the MLA in 30 U.S.C. 226(b)(1), as amended, authorizing BLM to conduct onshore lease sales through internet-based bidding methods.

B. Regulatory Planning and Review (Executive Orders 12866 and 13563)

While Executive Order (E.O.) 12866 does not apply to "(r)egulations or rules that are limited to agency organization, management, or personnel matters,'' it does not exempt those rules that describe the procedure or practice requirements of an agency. E.O. 12866, Sec. 3(d). The E.O. provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. Because this rule does not meet any of the standards for a significant regulatory action in E.O. 12866, this rule is not significant for purposes of the E.O. *See* E.O. 12866, Sec. 3(f).

E.O. 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the nation's regulatory system to promote predictability, reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory objectives. This E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas, where appropriate. The BLM developed this rule in a manner consistent with these requirements.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. However, the RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). Because no notice of proposed rulemaking is required, the RFA does not require an initial or final regulatory flexibility analysis of this rule.

D. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2) of the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, Indian, or local government agencies or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

This rule merely makes procedural changes involving agency organization, procedure, or practice, by adding the option, consistent with applicable statutory authority, for the BLM to use internet-based bidding in addition to oral auctions for its competitive oil and gas lease sales.

E. Unfunded Mandates Reform Act

Under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.*, agencies must prepare a written statement about benefits and costs prior to issuing a proposed or final rule that may result in aggregate expenditures by State, local, and tribal governments or by the private sector of $100 million or more in any one year. This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. This rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. Since this rule is not an unfunded mandate, the BLM is not required to provide a statement containing the information that the Unfunded Mandates Reform Act requires.

F. Takings (E.O. 12630)

Under the criteria in section 2 of E.O. 12630, this rule does not have any significant takings implications. This rule will not impose conditions or limitations on the use of any private property. Therefore, this rule does not require a Takings Implication Assessment.

G. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have Federalism implications that warrant the preparation of a Federalism summary impact statement. The management of Federal mineral leases is the responsibility of the Secretary of the Interior. This rule does not impose administrative costs on States or local governments. This rule also does not substantially and directly affect the relationship between the Federal and State governments. Because this rule does not alter that relationship, this rule does not require a Federalism summary impact statement.

H. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

a. Meets the criteria of section 3(a), which requires that agencies review all regulations to eliminate errors and ambiguity and write them to minimize litigation.

b. Meets the criteria of section 3(b)(2), which requires that agencies write all regulations in clear language using clear legal standards.

I. Consultation With Indian Tribal Governments (E.O. 13175)

Under E.O. 13175, the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951, May 4, 1994), the Department of the Interior (DOI) Policy on Consultation with Indian Tribes (Dec. 1, 2011), and the DOI Departmental Manual, part 512, section 2, the BLM evaluated possible effects of the rule on Federally recognized Indian tribes. The DOI strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. The BLM determined that this rule has no tribal implications because the BLM does not conduct oil and gas lease sales for Indian tribal, corporate, or allotted lands. Thus, Indian tribal governments are not impacted by the changes made by this rule, and consultation is not required.

J. Paperwork Reduction Act of 1995

This rule will modify 43 CFR 3103.3–2, 3110.1, 3110.2, 3120.1–2, 3120.3–7, 3120.5–1, 3120.5–2, 3120.5–3, and 3120.6 to recognize that the BLM is statutorily authorized to use either oral or internet-based auctions to conduct its oil and gas lease sales. None of these regulations has required an Office of Management and Budget (OMB) control number in the past, nor do they require an OMB control number as revised. They are within 5 CFR 1320.3(h)(1), which provides an exception from Paperwork Reduction Act requirements for affirmations, certifications, or acknowledgements as long as they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. This rule does not contain any new information collection requirements, and therefore, does not require a submission to the OMB under the Paperwork Reduction Act.

K. National Environmental Policy Act

This rule is procedural in nature; therefore, it qualifies for categorical exclusion under 43 CFR 46.210(i). As a result, a detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required. The BLM has also determined that this rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA, even though a categorical exclusion exists. Moreover, this rule does not constitute a major Federal action significantly affecting the quality of the human environment, as the procedural changes resulting from these amendments will have no effect on the physical environment. The rule only expands the methods the BLM may use to conduct an oil and gas leases sale; it does not modify the standards or requirements the BLM applies when deciding to offer a particular parcel for lease.

L. Effects on the Nation's Energy Supply (E.O. 13211)

Under E.O. 13211, agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions. This Statement must include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action, and reasonable alternatives and their effects. Section 4(b) of E.O. 13211 defines a "significant energy action" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of OIRA as a significant energy action." This rule will not have any adverse effects on energy supply, distribution, or use and is therefore not a significant energy action under the definition in E.O. 13211, and, therefore, a Statement of Energy Effects is not required.

List of Subjects

43 CFR Part 3100

Government contracts, Mineral royalties, Oil and gas reserves, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3110

Government contracts, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3120

Government contracts, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the BLM amends 43 CFR parts 3100, 3110, and 3120 as follows:

PART 3100—OIL AND GAS LEASING

■ 1. The authority citation for part 3100 is revised to read as follows:

Authority: 30 U.S.C. 189 and 359; 43 U.S.C. 1732(b), 1733, and 1740; the Energy Policy Act of 2005 (Pub. L. 109–58); and the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291, 128 Stat. 3762).

Subpart 3103—Fees, Rentals and Royalty

■ 2. In § 3103.3–2, revise paragraph (a)(2) to read as follows:

§ 3103.3–2 Minimum royalties.

(a) * * *

(2) On leases issued from offers filed after December 22, 1987, and on competitive leases issued from successful bids placed at oral or internet-based auctions conducted after December 22, 1987, a minimum royalty in lieu of rental of not less than the amount of rental which otherwise would be required for that lease year.

* * * * *

PART 3110—NONCOMPETITIVE LEASES

■ 3. The authority citation for part 3110 is revised to read as follows:

Authority: 16 U.S.C. 3101 *et seq.;* 30 U.S.C. 181 *et seq.* and 351–359; 31 U.S.C. 9701; 43 U.S.C. 1701 *et seq.;* Pub. L. 97–35 Stat. 357; and the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291, 128 Stat. 3762).

Subpart 3110—Noncompetitive Leases

■ 4. In § 3110.1, revise the second sentence of paragraph (b) to read as follows:

§ 3110.1 Lands available for noncompetitive offer and lease.

* * * * *

(b) * * * Such lands shall become available for a period of 2 years beginning on the first business day following the last day of the competitive oral or internet-based auction, or when formal nominations have been requested as specified in § 3120.3–1 of this title, or the first business day following the posting of the Notice of Competitive Lease Sale, and ending on that same day 2 years later. * * *

■ 5. In § 3110.2, revise the first sentence of paragraph (a) to read as follows:

§ 3110.2 Priority.

(a) Offers filed for lands available for noncompetitive offer or lease, as specified in §§ 3110.1(a)(1) and 3110.1(b) of this title, shall receive priority as of the date and time of filing as specified in § 1821.2–3(a) of this title, except that all noncompetitive offers shall be considered simultaneously filed if received in the proper BLM office any time during the first business day following the last day of the competitive oral or internet-based auction, or when formal nominations have been requested as specified in § 3120.3–1 of this title, on the first business day following the posting of the Notice of Competitive Lease Sale. * * *

* * * * *

PART 3120—COMPETITIVE LEASES

■ 6. The authority citation for part 3120 is revised to read as follows:

Authority: 16 U.S.C. 3101 *et seq.;* 30 U.S.C. 181 *et seq.* and 351–359; 40 U.S.C. 471 *et seq.;* 43 U.S.C. 1701 *et seq.;* the Attorney General's Opinion of April 2, 1941 (40 Op. Atty. Gen. 41); and the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291, 128 Stat. 3762).

Subpart 3120—Competitive Leases

■ 7. In § 3120.1–2, revise paragraph (b) to read as follows:

§ 3120.1–2 Requirements.

* * * * *

(b) Lease sales shall be conducted by a competitive oral or internet-based bidding process.

* * * * *

■ 8. Revise § 3120.3–7 to read as follows:

§ 3120.3–7 Refund.

The minimum bid, first year's rental and administrative fee shall be refunded to all nominators who are unsuccessful at the oral or internet-based auction.

■ 9. Amend § 3120.5–1 by revising the section heading;, the first sentence of paragraph (a), the first sentence of paragraph (b), and paragraph (c) to read as follows:

§ 3120.5–1 Oral or Internet-based auction.

(a) Parcels shall be offered by oral or internet-based bidding. * * *

(b) A winning bid shall be the highest oral or internet-based bid by a qualified bidder, equal to or exceeding the national minimum acceptable bid.

* * *

(c) Two or more nominations on the same parcel when the bids are equal to the national minimum acceptable bid, with no higher oral or internet-based bid being made, shall be returned with all moneys refunded. If the Bureau reoffers the parcel, it shall be reoffered only competitively under this subpart with any noncompetitive offer filed under § 3110.1(a) of this title retaining priority, provided no bid is received at an oral or internet-based auction.

■ 10. In § 3120.5–2, revise paragraph (c) to read as follows:

§ 3120.5–2 Payments required.

* * * * *

(c) The winning bidder shall submit the balance of the bonus bid to the proper BLM office within 10 working days after the last day of the oral or internet-based auction.

■ 11. In § 3120.5–3, revise paragraph (c) to read as follows:

§ 3120.5–3 Award of lease.

* * * * *

(c) If a bid is rejected, the land shall be reoffered competitively under this subpart with any noncompetitive offer filed under § 3110.1(a) of this title retaining priority, provided no bid is received in an oral or internet-based auction.

* * * * *

■ 12. Revise § 3120.6 to read as follows:

§ 3120.6 Parcels not bid on at auction.

Lands offered at the oral or internet-based auction that received no bids shall be available for filing for noncompetitive lease for a 2-year period beginning the first business day following the auction at a time specified in the Notice of Competitive Lease Sale.

Dated: August 24, 2016.

Amanda C. Leiter,

Acting Assistant Secretary, Land and Minerals Management.

[FR Doc. 2016–20943 Filed 8–30–16; 8:45 am]

BILLING CODE 4310–84–P

Proposed Rules

Federal Register
Vol. 81, No. 169
Wednesday, August 31, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AM40

Access to Federal Employees Health Benefits (FEHB) for Employees of Certain Indian Tribal Employers

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a Notice of Proposed Rulemaking to address the implementation of certain provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, as amended (ACA) making Federal employee health insurance accessible to employees of certain Indian tribal entities. The ACA includes authorization for Indian tribes, tribal organizations, and urban Indian organizations that carry out certain programs to purchase coverage, rights, and benefits under the Federal Employees Health Benefits (FEHB) Program for their employees. Tribal employers and tribal employees will be responsible for the full cost of benefits, plus an administrative fee.

DATES: *Comment date:* Comments are due on or before October 31, 2016.

FOR FURTHER INFORMATION CONTACT: Chelsea Ruediger, Senior Policy Analyst (202) 606–0004.

ADDRESSES: You may submit comments, identified by RIN number "3206–AM40" using any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Chelsea Ruediger, Senior Policy Analyst, Planning and Policy Analysis, U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Office of Personnel Management (OPM) is issuing a notice of proposed rulemaking to extend certain Federal employee benefits to employees of certain Indian tribal employers. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), as amended (ACA) extended eligibility to purchase coverage, rights, and benefits under the Federal Employees Health Benefits (FEHB) Program to employees of those Indian tribes and tribal organizations carrying out programs under the Indian Self-Determination and Education Assistance Act (ISDEAA), and urban Indian organizations carrying out programs under title V of the Indian Health Care Improvement Act (IHCIA). This regulation includes program rules for tribal employers and tribal employees in accordance with chapter 89 of title 5, United States Code. The new regulatory provisions are set forth in new subpart N, part 890 of title 5 of the Code of Federal Regulations.

These proposed rules, which codify previously issued guidance, adopt the FEHB program for Federal employees under 5 U.S.C. 89 with slight variations to meet the needs of the tribal population. OPM performed consultation and developed sub-regulatory guidance in 2011–2012 to administer the program. OPM has been operating the program since then and tribal employers began purchasing FEHB for their employees on March 22, 2012 with an insurance coverage effective date of May 1, 2012. As of the publication date of this proposed rule, 19,540 tribal employees and 90 tribes are participating in the program. These proposed rules codify the program as set forth in previous guidance after extensive work understanding tribal population needs.

Authorizing Legislation

Section 10221 of the ACA enacted the entire text of S. 1790 as reported on December 16, 2009 by the Senate Committee on Indian Affairs to Public Law 111–148. S. 1790 revised and extended the IHCIA, including adding a new section 409 to the IHCIA (codified at 25 U.S.C. 1647b).

This proposed regulation refers to tribes, tribal organizations, and urban Indian organizations that are entitled to access insurance under section 409 as "tribal employers." Moreover, because the term "employee" as used in 5 U.S.C. chapter 89 is a statutorily defined term, OPM refers to a tribal employer's employees who are eligible to enroll in FEHB as "tribal employees."[1] This proposed regulation establishes how FEHB enrollment will be administered, including eligibility, tribal employer and tribal employee contribution to premiums, the process by which tribal employers will access these programs, the process by which tribal employees will elect coverage, and circumstances for termination and cancellation of enrollment.

Where practicable, this regulation provides for the administration of benefits by and for tribal employers and tribal employees in the same manner as these benefits are administered by and for Federal agencies and Federal employees. There may be some instances for which there is no established procedure in place for the Federal Government, such as the procedure and timeline by which tribal employers certify entitlement to purchase FEHB. When there are no established procedures in place, OPM has proposed a procedure.

OPM has worked in consultation with tribal leaders to establish program rules.

Tribal Consultation

Under Executive Order 13175, OPM has an obligation to engage in "regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications." OPM is committed to fulfilling this obligation.

Following the passage of the ACA, OPM published a series of policy papers

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[1] The ACA establishes entitlement for certain tribal employers to purchase FEHB coverage, rights, and benefits for their tribal employees in a manner consistent with the FEHB statute 5 U.S.C. Ch. 89. The Department of Labor reviewed this notice of proposed rulemaking and advised that the tribal employer does not "establish or maintain" an employee welfare benefit subject to Title I of ERISA with such a purchase pursuant to the ACA, and advised that the enrollment of tribal employees in FEHB coverage does not affect the status of the FEHB as a governmental plan for purposes of the exemption from title I of ERISA at 29 U.S.C. 1003(b)(1). In addition, the Department of the Treasury, including the Internal Revenue Service, reviewed this notice of proposed rulemaking and advised that the enrollment of tribal employees in FEHB coverage does not affect the status of the FEHB as a governmental plan within the meaning of 26 U.S.C. 9832(d)(2).

(found here under Outreach Documentation) regarding the implementation of the Tribal FEHB Program. Tribes, tribal organizations, and urban Indian organizations were given an opportunity to provide feedback on these papers at outreach events and tribal conferences and meetings. Written feedback was also accepted.

A Tribal Technical Workgroup composed of tribal human resource representatives and OPM operational and policy staff was established when developing this regulation and in support of the implementation of the Tribal FEHB Program. The primary purpose was to ensure system requirements for enrollment processing were completed according to the needs of tribal employers.

Additional tribal consultative actions included collaborating with the Department of Health and Human Services (HHS) to conduct in-person briefings for tribal communities across the country, focusing on the implementation of the ACA.

OPM representatives have attended more than 20 tribal conferences and meetings to provide information and consultation about the Tribal FEHB Program since its inception. In addition, OPM has hosted training sessions for interested tribes and tribal organizations on numerous occasions. Tribal Benefits Administration Letters (TBAL) are released and distributed to participating tribal employers regularly, just as they are for Federal agencies. Questions following the release of a TBAL are directed to OPM's dedicated Tribal Desk. The Tribal Desk is available during regular business hours and is answered by the OPM staff who administer the program. Whenever possible, OPM has created direct lines of communication and fostered collaboration between tribal employers and OPM employees.

When important program changes occur, OPM issues Dear Tribal Leader Letters (DTLL) to notify tribes, tribal organizations and urban Indian organizations. An example was the DTLL issued describing the revision of the original "all-or-nothing" policy. The original policy had required a tribal employer to enroll all of their billing units. Due to concerns raised by tribal employers, OPM amended that policy to allow tribal employers to select which of their billing units will receive FEHB and which will not. As a result, interest in FEHB enrollment has increased.

OPM's obligation to consult with tribal officials is ongoing. OPM will consider the public comment period of this proposed rule as an important consultation period. Tribal leaders will be alerted of the publication of this proposed rule and the process for submitting formal comments with a DTLL. As appropriate, OPM will conduct meetings with tribal officials to address components of this proposed rule. A DTLL will also be issued in tandem with the publication of a final rule.

FEHB Background

The FEHB Program was established in 1960 to provide health benefits to Federal employees, annuitants, spouses, and children. Approximately 8.2 million employees, annuitants, and family members are now covered. Federal employees can choose among various forms of health plans, including nationwide Fee-for-Service (FFS) plans, local Health Maintenance Organizations (HMO), Consumer-Driven Health Plans (CDHP), and High-Deductible Health Plans (HDHP). FEHB plans typically cover inpatient and outpatient hospital care, primary care and specialist doctor visits, and pharmacy benefits. Some FEHB plans offer limited routine vision and dental benefits.

Currently, there are three FEHB enrollment categories: (1) Self only; (2) self plus one; and (3) self and family. A self only enrollment covers only the enrollee. A self plus one enrollment covers the enrollee and one designated eligible family member. A self and family enrollment covers the enrollee and all eligible family members. Eligible family members include a spouse and/or child(ren) under age 26 (including married children, adopted children, and stepchildren). A child age 26 or over who is incapable of self-support because of a mental or physical disability that existed before age 26 is also an eligible family member. A foster child may be covered if the child lives with the employee in a parent-child relationship and the employee expects to raise the child to adulthood.

A newly eligible Federal employee can enroll in any FEHB plan available in his or her geographic region within 60 days of becoming eligible. FEHB coverage is effective the first day of the pay period after the enrollment request is received by the Federal employee's employing office and that follows a pay period during any part of which the employee is in pay status. Federal employees can enroll, cancel enrollment, increase or decrease enrollment, or change plans or options during the annual open season usually held from mid-November to mid-December. Any changes made during open season are effective for the following calendar year. Enrollees can also change enrollment in conjunction with a qualifying life event (QLE), such as marriage, divorce, birth or adoption of a child, change in employment status that affects insurance coverage or cost, or a move outside of an HMO's service area.

The employing Federal agency pays a Government contribution of approximately 72 percent of the weighted average of premiums in effect for each calendar year. The Government contribution to any individual plan is capped at 75 percent of premium. FEHB plans generally require enrollee cost sharing in the form of calendar year deductibles, copayments, and/or coinsurance for covered services.

Definitions

Section 890.1402 defines several terms used in the new subpart N of Part 890. This section also includes a series of deemed references. Defining these terms and identifying deemed references are necessary to make clear how OPM will modify and apply existing regulations to govern tribal employers' purchase of FEHB for tribal employees.

The new subpart N refers to and incorporates many other subparts of part 890 that govern how the FEHB Program functions. The deemed references make it clear that references to statutory terms such as "employee," and other terms used throughout part 890 will be deemed references to "tribal employee," and other terms as appropriate, in context, to govern tribal employers' purchase of FEHB for its tribal employees pursuant to the ACA.

Scope of Entitlement for Tribal Employers

Entitlement to offer FEHB coverage, rights, and benefits will be available to any tribe, tribal organization, or urban Indian organization carrying out at least one of the programs under the ISDEAA or Title V of the IHCIA as specified in section 409 of the IHCIA. The terms "tribe," "tribal organization," and "urban Indian organization" are defined in the IHCIA. Those definitions, set forth below, are incorporated by reference in the regulatory text at § 890.1402 which defines the term "tribal employer." The term "tribal employer" is used to refer to any of these entities that fulfill the requirements to be entitled to purchase FEHB for its employees.

A tribe is any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska

Native Claims Settlement Act (85 Stat. 688) [43 U.S.C.A. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. 25 U.S.C. 1603(14).

A tribal organization is the recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: That in any case in which a contract is let or grant made to an organization to perform services benefiting more than one Indian tribe, the approval of each such Indian tribe shall be a prerequisite to the letting or making of such contract or grant. 25 U.S.C. 1603(26), incorporating by reference 25 U.S.C. 450b(l) (definition of "tribal organization").

An urban Indian organization is a non-profit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in section 1653(a) of this title. 25 U.S.C. 1603(29).

For purposes of this regulation, tribes and tribal organizations carrying out at least one program under the ISDEAA, and urban Indian organizations carrying out at least one program under Title V of the IHCIA, are entitled to purchase FEHB for their employees. If the tribal employer ceases to carry out one of these programs, entitlement to purchase FEHB ceases at the end of the calendar year in which the tribal employer ceased to carry out one of those programs.

If OPM determines that a tribal employer is not entitled to purchase FEHB, the tribal employer may appeal that decision to OPM. OPM retains sole authority for deciding entitlement.

Eligible Tribal Employees

OPM has defined the term "tribal employee" in § 890.1402 broadly to mean a common law employee of a tribal employer. This section incorporates the regulatory standard under the Federal employment tax regulations, (which, for this purpose, includes Federal Insurance Contributions Act tax and Federal income tax withholding), which generally provides that an individual is a common law employee if the tribal employer has the right to control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the details and means by which that result is accomplished. This determination is based on all the facts and circumstances. The section then indicates that this determination is to be guided by a list of 20 factors[2] developed by the Internal Revenue Service (IRS), or any future guidance the IRS releases related to the common law employee relationship for Federal employment tax purposes. Because OPM expects tribal employers to treat tribal employees consistently for purposes of Federal employment taxation and access to Federal insurance, the tribal employer's determination of common law employee status for purposes of eligibility for FEHB must be consistent with any determination of common law employee status made by the tribal employer for Federal employment tax purposes.

OPM recognizes that there may be very limited cases in which a tribal employer has determined that a worker is a common law employee but has also determined that no Federal employment taxes are due with respect to the worker. Under these circumstances, OPM will defer to the tribal employer's reasonable determination that the worker is a common law employee for purposes of eligibility to enroll in FEHB.

Each tribal employer entitled to access Federal insurance will be able to offer FEHB coverage, rights, and benefits to all of its tribal employees, not just those carrying out functions under the ISDEAA or IHCIA title V programs. OPM has determined that tribal employees (who, by definition, are common law employees) engaged in governmental or commercial operations, such as casino or hospitality operations, will be eligible to enroll in FEHB if it is purchased by their tribal employer. As discussed below, individuals who retire from employment with a tribal employer lose their status as tribal employees upon retirement and their enrollment will terminate.

A tribal employer carrying out programs under the ISDEAA or Title V of the IHCIA may purchase FEHB for employees of one or more billing units carrying out programs or activities under their contract. Once a tribal employer has enrolled at least one billing unit carrying out programs or activities under ISDEAA or IHCIA, the tribal employer may enroll one or more billing units that are not carrying out programs or activities under ISDEAA or IHCIA. Section 890.1405 establishes that all eligible full-time and part-time tribal employees of each participating billing unit of a tribal employer must be offered the opportunity to enroll in FEHB. Intermittent, seasonal, and temporary tribal employees will be treated similarly to intermittent, seasonal and temporary Federal employees. However, under § 890.102(k), the tribal employer may choose not to extend coverage to certain intermittent, seasonal, and temporary employees if written notification is provided to the Director of OPM.

Tribal employers may not segment tribal employee populations by offering a different set of health benefits to different groups of tribal employees within a single billing unit. An exception to this rule is if tribal employees within a billing unit are offered alternative coverage as part of a collective bargaining agreement.

Coverage of Family Members

As described in § 890.1405(e), family members of tribal employees will be eligible for coverage in FEHB under substantially the same terms as family members of Federal employees. One exception is that former spouses of tribal employees may not enroll in FEHB under the Civil Service Retirement Spouse Equity Act. This is because Spouse Equity coverage is linked to the former spouse's entitlement to a portion of a Federal employee's annuity. Another exception is that if the tribal employee dies while employed, a surviving spouse cannot continue FEHB enrollment or enroll in his or her own right, unless the surviving spouse is also FEHB-eligible through his or her employment. This is because continuing FEHB eligibility for surviving spouses of Federal employees is linked to a survivor annuity.

Section 890.1406 states that correction of enrollment errors will take place according to the same terms as for Federal employees. Requirements for tribal employees' appeals of eligibility and enrollment decisions are described in § 890.1415.

Tribal Employer and Tribal Employee Contributions and Administrative Fee

Section 890.1403 explains that a tribal employer is entitled to purchase FEHB if payment, defined by § 890.1402 as all premiums plus administrative fees, are currently deposited in the Employees Health Benefits Fund, as required by the authorizing statute. This section provides that a payment will be considered "currently deposited" if it is received by the Fund before, during, or within fourteen days after the end of the calendar month covered by the payment.

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[2] IRS in Rev. Rul. 87–41, 1987–1 C.B. 296 and referenced in Joint Committee on Taxation report JCX–26–07 *"Present Law and Background Relating to Worker Classification for Federal Tax Purposes,"* dated May 7, 2007 *http://www.irs.gov/pub/irs-utl/x-26-07.pdf.*

Section 890.1413 describes how payment will work for tribal employers participating in FEHB. Tribal employer and tribal employee contributions for FEHB will be handled similarly for tribal employees as for Federal employees, with the tribal employer responsible for contributing a share of premium that is at least equivalent to the share of premium that the Federal Government contributes for Federal employees. The percentage contribution requirements are described in 5 U.S.C. 8906. The FEHB contributions for part-time tribal employees working between 16 and 32 hours per week may be pro-rated in accordance with the terms applicable to part-time Federal employees. FEHB enrollment for tribal employees on unpaid leave may be continued in a manner similar to Federal employees on unpaid leave under 5 CFR 890.502(b), as long as the full premium is paid.

The tribal employer's FEHB contribution percentage must equal or exceed the contribution that the Federal Government would make each month for a Federal employee for the same plan. Tribal employers may elect to pay a greater tribal employer contribution, but may not pay a lesser amount than the Federal Government contribution for each plan. There is no cap on the percentage of premium that a tribal employer may contribute. The tribal employer may vary the contribution by type of enrollment (self only, self plus one, self and family) but must treat tribal employees in a uniform manner. As an example, a tribal employer could contribute 100% for all tribal employees in self only or self plus one enrollments and 90% for all tribal employees in self and family enrollments. Tribal employers may not vary the tribal employer contribution in order to encourage or discourage enrollment in any particular plan or plan option. Tribal employers may choose to vary the contribution amounts for each billing unit, provided each billing unit meets the requirements set forth above.

In addition, the tribal employer is required to pay an administrative fee, in an amount set by OPM each year, for each tribal employee's enrollment on a monthly basis. This fee covers the costs of a paymaster to perform the collection and remittance functions that is performed for Federal employees by Federal payroll offices. The paymaster is the entity designated by OPM as responsible for receiving FEHB premiums from the tribal employer, forwarding premiums to the Employees Health Benefits Fund, and maintaining enrollment records for all participating tribal employers. Tribal employers may not charge this fee to tribal employees. The total aggregate amount for tribal employees' and tribal employer's share of the premium and the administrative fee must be available for receipt by the paymaster on an agreed upon date set in the agreement with the tribal employer.

Tribal Employers' Entitlement and Election to Purchase FEHB

Section 890.1404 establishes a process by which tribal employers may demonstrate entitlement and elect to purchase, FEHB for their tribal employees. The tribal employer must notify OPM by email or telephone of the intention to purchase FEHB. Through an agreement described in § 890.1404(b), OPM will confirm: (1) The tribal employer's contact information; (2) the date that FEHB coverage will begin; (3) the approximate number of tribal employees eligible to enroll; (4) the tribal employer's agreement not to make available to FEHB-eligible tribal employees alternate tribal employer-sponsored health insurance coverage concurrent with FEHB; (5) the tribal employer is entitled to participate in the FEHB by carrying out at least one program under ISDEAA or title V of IHCIA; (6) the tribal employer's acknowledgement that participation in FEHB makes the tribal employer subject to Federal Government audit with respect to such participation and to OPM authority to direct the administration of the program; (7) the tribal employer's agreement to establish or identify an independent dispute resolution panel to adjudicate appeals of determinations made by a tribal employer regarding an individual's status as a tribal employee; (8) the tribal employer's agreement to supply necessary enrollment information, payment of the tribal employer and tribal employee share of premium and payment of an administrative fee to the paymaster; (9) the tribal employer's agreement to notify OPM in the event that the tribal employer is no longer carrying out at least one program under the ISDEAA or title V of IHCIA, and (10) the tribal employer's agreement to abide by other terms and conditions of participation.

Section 890.1404(c) allows a tribal employer to elect to purchase FEHB at any time. The election to purchase FEHB will commit the tribal employer to purchase FEHB at least through the remainder of the calendar year in which the election is made. Elections will be automatically renewable year to year unless revoked by the tribal employer or terminated by OPM. Section 890.1404(d) allows a tribal employer to revoke its election to purchase FEHB with 60 days' notice to OPM. If a tribal employer revokes an election to purchase FEHB, that tribal employer may only re-elect to purchase FEHB during the first annual open enrollment season that occurs at least twelve months after the election is revoked. If the tribal employer revokes an election to participate a second time, the tribal employer may only re-elect to purchase FEHB during the first open season that falls at least twenty-four months after the second revocation. Section 890.1404(f) states that OPM maintains final authority to determine entitlement of a tribal employer to purchase FEHB.

A tribal employer that begins to carry out a program under ISDEAA or Title V of IHCIA after this rule is effective may notify OPM of its intention to purchase benefits after the entitlement is established. Section 890.1407 states that a tribal employer electing to purchase FEHB for its employees may not concurrently make contributions toward non-FEHB tribal employer-sponsored health insurance to any tribal employee eligible for FEHB. However, a tribal employer electing FEHB may concurrently offer non-FEHB dental, vision, or disability coverage. This requirement will keep tribal employees' enrollment conditions aligned with those of Federal employees.

Interaction With Other FEHB Coverage

Section 890.1405(f) establishes that eligibility to enroll in FEHB does not cause any tribal employee to be identified or characterized as a Federal employee, nor does it convey any additional rights or privileges of Federal employment. There may be circumstances in which a tribal employee is also an FEHB-eligible Federal employee. In such a case, the tribal employee may participate in FEHB through either employer. A tribal employee who is also a Federal employee cannot enroll in FEHB through both employers. FEHB enrollments may be transferred between Federal employing offices and tribal employers in a similar manner as transfer of enrollments between Federal agencies.

Initial Tribal Employee Enrollment Period, Open Season, and QLEs

Section 890.1405 describes tribal employee eligibility for enrollment in FEHB. Tribal employees will be able to enroll in FEHB after an agreement between the tribal employer and OPM is signed. The effective date of coverage will be decided by the tribal employer and OPM. A third party paymaster will handle payroll functions including remitting tribal employer and tribal employee contributions to FEHB premiums.

The enrollment process for tribal employees into FEHB is described in § 890.1407. Tribal employers must establish an initial enrollment opportunity for tribal employees. After that initial enrollment opportunity, for plan years during which a tribal employer's election to offer FEHB is in place, the FEHB enrollment period for tribal employees will be the same as for Federal employees: Up to 60 days after becoming a new tribal employee or changing to an eligible position, during the annual open season, or 31 days before to 60 days after experiencing a qualifying life event. The effective date of enrollment for tribal employees will be the same as for Federal employees under parts 890 or 892, depending on premium conversion status. Upon enrollment in the FEHB Program, tribal employees will choose among the same nationwide and local FEHB plans that are available to Federal employees.

Section 890.1408 describes the circumstances under which a tribal employee may change enrollment type, plan, or option. These changes are allowed and will take effect under the same circumstances as for Federal employees. Changes may be restricted if the tribal employer has a premium conversion plan in effect (pre-tax treatment of premiums) and the tribal employee has elected premium conversion.

Cancellation of Coverage, Decreases in Enrollment

Section 890.1409 establishes that a tribal employee may cancel his or her FEHB coverage or decrease his or her enrollment only under the same circumstances as a Federal employee. If the tribal employee has elected premium conversion, this cancellation or change is restricted.

Termination of Enrollment

Section 890.1410 establishes that FEHB enrollment will terminate when employment with the tribal employer ends due to resignation, dismissal, or retirement, or when the tribal employer discontinues its purchase of FEHB. Termination of enrollment does not refer to a voluntary cancellation by the tribal employee during a period of continued employment. Upon termination of enrollment, the tribal employee will receive a 31-day temporary extension of coverage without premium contribution from the tribal employee or tribal employer and will have an opportunity to convert to an individual policy. Tribal employees whose FEHB enrollment terminates due to separation from tribal employment (unless the separation is for gross misconduct) are also eligible for temporary continuation of FEHB coverage (TCC), described at 5 U.S.C. 8905a and 5 CFR part 890 subpart K.

If an FEHB enrollment is terminated due to the death of the tribal employee, the tribal employee's spouse and covered children are entitled to a 31-day temporary extension of coverage and opportunity to convert to an individual policy. Covered children, if any, may elect TCC and may cover the tribal employee's surviving spouse as a member of family.

Termination Due to Non-Payment of Premiums

Section 890.1410(f) establishes that insufficient payment from the tribal employer to the paymaster can result in termination of enrollment for all of the tribal employer's tribal employees affected by the paymaster's failure to obtain current deposit. In such a case, FEHB enrollment for all affected tribal employees will be terminated according to a process determined by OPM. FEHB enrollment of all tribal employees affected by the paymaster's failure to obtain current deposit will be terminated effective as of midnight on the last day of the month in which premium payment was received. These tribal employees will be entitled to a 31-day temporary extension of coverage without additional premium contribution and the opportunity to convert to an individual policy. In the event that a tribal employer elects to purchase FEHB and does not pay premiums for the first month in which payment is due, no 31-day temporary extension of coverage or opportunity to convert to an individual policy will be provided. Termination of enrollment due to non-payment of premiums in either case will not result in an opportunity to enroll in TCC since current tribal employees do not meet the conditions for TCC enrollment. Tribal employers will have full responsibility for communicating notice of termination of enrollment, and accompanying rights and obligations, to their tribal employees. Any outstanding premium due for coverage in arrears will be treated as a debt owed solely by the tribal employer.

Temporary Continuation of Coverage (TCC)

Tribal employees and certain family members whose FEHB coverage terminates under certain circumstances can elect to purchase temporary continuation of coverage (TCC) for up to 18 or 36 months. Section 890.1411 establishes the criteria for TCC participation for tribal employees and their family members. In general, tribal employees who are enrolled in FEHB and separate from tribal employment, except for reasons of gross misconduct, may elect to purchase TCC. Certain formerly covered family members, including children or stepchildren who no longer meet the requirements of a covered family member, and former spouses, may elect TCC. The surviving spouse of a deceased enrollee who was enrolled in FEHB is not eligible to elect TCC, but may be covered by the TCC enrollment of an eligible child.

The administrative fee is the same as would apply to a former Federal employee enrolled in TCC. The administrative fee described in § 890.1413(e) would not apply to a TCC enrollment of a tribal employee or family member.

Non-Pay Status, Insufficient Pay, or Change to Ineligible Position

Section 890.1412 establishes that a tribal employee in non-pay status or with insufficient pay to cover the premium costs may continue FEHB enrollment for up to 365 days. Tribal employees in non-pay status due to uniformed service are entitled to continue FEHB enrollment for up to 24 months. After termination, the tribal employee and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution, and conversion to an individual policy.

Section 890.1412 also establishes that a temporary tribal employee who has insufficient pay to cover the employee share of FEHB premiums may choose a less expensive plan. If the tribal employee does not or cannot move to a less expensive plan, the FEHB enrollment will be terminated and the enrollee is entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy.

If a tribal employee moves from an FEHB-eligible to a FEHB ineligible position, the FEHB enrollment can continue if there has not been a break in service of more than three days. If there has been a break in service of longer than three days, FEHB enrollment will terminate at midnight of the last day of the pay period in which the employment status changed. Such a tribal employee will be entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy.

Responsibilities of the Tribal Employer

Section 890.1414 describes the responsibilities of the tribal employer. These include premium payment, eligibility determinations, enrollment, establishment of appeals process, communications regarding FEHB, and notification requirements.

Eligibility and Enrollment Decisions and Appeal Rights

Section 890.1415 requires that a tribal employer establish or identify an independent panel to resolve disputes about eligibility of individuals for FEHB enrollment. This panel must be authorized to adjudicate such disputes and enforce eligibility and enrollment determinations. The tribal employer must inform tribal employees of this avenue for dispute resolution. Decisions of the independent panel must be written, a record of evidence considered by the panel must be retained and available for OPM review, and the panel decisions remain subject to final OPM authority.

Filing Claims for Payment or Service; Court Review of Disputed Claims

Section 890.1416 describes the procedures for (1) filing claims for payment or service; and (2) invoking the provisions for court review of disputed claims. Both situations will follow the established procedures for Federal employees.

No Continuation of FEHB Enrollment Into Retirement From Employment With a Tribal Employer

Section 890.1417 states that an FEHB enrollment cannot be continued into retirement from employment with a tribal employer. This is a statutory requirement as the law entitles tribal employers to purchase FEHB for employees but it does not extend that entitlement to permit tribal employers to purchase FEHB for retirees.

A Federal annuitant may continue FEHB into retirement and any enrollment in, or coverage as a family member under FEHB during employment with a tribal employer will count toward the "five-year rule." The "five-year rule" generally requires five years of pre-retirement FEHB enrollment, or coverage as a family member, in order to continue FEHB into retirement. Section 890.1417 further states that a Federal annuitant who has continued FEHB into retirement and who begins post-retirement employment with a tribal employer that has elected to purchase FEHB may transfer the FEHB enrollment with his or her Federal retirement system to an enrollment with the tribal employer in a similar manner as that used for Federal annuitants re-employed by Federal agencies.

No Continuation of FEHB Enrollment for Compensationers Past 365 days

Section 890.1418 establishes that tribal employees who are not also Federal employees, but are receiving worker's compensation benefits in leave without pay status for more than 365 days under programs run by the U.S. Department of Labor may not be enrolled in FEHB.

Regulatory Impact Analysis

OPM has examined the impact of this proposed rule as required by Executive Order 12866 and Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity), and based on that analysis, it has determined that it is an economically significant rule. A regulatory impact analysis must be prepared for economically significant rules.

Need for Regulatory Action

As part of the ACA, section 10221 incorporated and enacted S. 1790, the Indian Health Care Improvement Reauthorization and Extension Act of 2009, resulting in the addition of section 409 to the IHCIA. Section 409 allows tribes, tribal organizations and urban Indian organizations carrying out specific programs under Federal law to purchase the rights and benefits FEHB Program for their employees. As the administrator of the FEHB, OPM has extended eligibility to entitled tribal employees within the meaning of section 409. Section 409 has been implemented and over 16,000 tribal employees are currently covered by FEHB. Federal regulations are necessary to protect the interests of all stakeholders, memorialize processes and procedures, and provide transparency.

Regulatory Baseline

The costs, benefits and transfers assessed in remaining portions of this regulatory impact analysis reflect existing FEHB coverage of tribal employees. This analysis is consistent with the guidance provided in OMB Circular A–4.

Benefits of Coverage

Health insurance coverage improves access to health care services, including preventive services, improves clinical outcomes, financial security, and decreases uncompensated care.[3] Although section 409 extends FEHB to employees of tribes, tribal organizations, and urban Indian organizations regardless of their status as tribal members, the authorizing legislation for this regulation falls under 25 U.S.C. Chapter 18 which clearly outlines congressional intent to "maintain and improve the health of the Indians" and identifies providing "the resources, processes, and structure that will enable Indian tribes and tribal members to obtain the quantity and quality of health care services and opportunities that will eradicate the health disparities between Indians and the general population of the United States" as a major national goal of the United States (section 1601). Thus, the following section discusses the benefits of extending health insurance to tribal members, rather than to tribal employees in general.

While the exact benefits of health insurance are difficult to quantify, evidence supports that American Indians and Alaska Natives could benefit more from health insurance than the average population. According to a 2013 Kaiser Family Foundation report, American Indians and Alaska Natives were more likely than other nonelderly adult Americans to report being in fair or poor health, being overweight or obese, having diabetes and cardiovascular disease, and experiencing frequent mental distress.[4] They had limited access to employer-sponsored coverage because more were unemployed or in low-wage jobs that did not offer health benefits. Almost a third of them were uninsured. More than 90% had incomes below 400% and 60% had incomes below 138% of the Federal poverty level. The infant mortality rate was 150 percent higher for Native American infants than white infants, and the suicide rate for Native

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[3] See Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, Exchange Standards for Employers (CMS–9989–FWP) and Standards Related to Reinsurance, Risk Corridors and Risk Adjustment (CMS–9975–F) for a more detailed description of the benefits of health insurance.

[4] Kaiser Family Foundation, "Health Coverage and Care for American Indians and Alaska Natives," October 2013.

Americans was two and a half times the national rate.[5]

The Indian Health Service (IHS), which provides services through a network of hospitals, clinics, and health stations to about 2.2 million American Indians and Alaska Natives, has historically been underfunded. Access to services varies significantly by location and funds are insufficient to meet health care needs. According to the Federal Disparity Index, in 2010 the IHS funds covered less than 60% of those needed to pay for coverage equivalent to that of Federal employees.[6]

Health services not available through direct care must be purchased through the Purchased/Referred Care (PRC) (formerly Contract Health Services)[7] program. Some estimates indicate that the PRC program has lost at least $778 million due to unfunded medical inflation and population growth between 1992 and 2008.[8] This has resulted in allocating of health care services using the PRC medical priority system, in which many patients cannot receive care unless they are in a priority status. In FY 2007, this under-funding resulted in a backlog of over 300,000 health services that were not provided because there was not enough funding. Unfortunately, the denied/deferred services report understates the need of PRC resources due to data limitations and the fact that many tribes no longer report deferred or denied services because of the expense involved in tracking.

The sources referenced above illustrate the health disparities specific to the Native American population. Expanding healthcare access to this group not only addresses this disparity and generates benefits to the individual, but also generates societal benefits in the form of decreased healthcare costs for chronic illnesses, increased employee productivity, and a healthier population that are the result of expanding access to healthcare to any group.

Costs of Coverage

In the following section, costs associated with this rule are analyzed for the following groups: Tribal employers, tribal employees, the Tribal Insurance Processing System (TIPS) (the system used by the current paymaster), OPM, and FEHB carriers. Most of the costs described below either result in a direct benefit to the individual or are transfers from one group to another. For example, costs incurred by tribal employees (premiums, deductibles, copays, etc.) result in individual benefits in the form of improved health outcomes. Costs incurred by tribal employers to cover premiums are a benefit to tribal employees. OPM has determined that the total dollar amounts do meet the threshold for this to be considered an economically significant rule.

OPM analyzed actual fiscal year 2015 enrollment data for the over 16,000 tribal employees enrolled in the FEHB Program and found the annual cost of enrollment to be $168.5 million. This includes both premiums and the administrative fee added to each tribal FEHB enrollment. The administrative fee covers the costs of program administration for the paymaster.[9] A per member per month (cost per month for each covered individual) cost of approximately $413 was calculated.[10]

Premiums in the FEHB Program have increased between 3–6% each year for the last five years, below increases in the commercial market. As enrollment increases, total spending on premium costs will increase. However, the administrative fee will likely decrease as administrative costs are spread among a growing number of enrollments.

Costs for Tribal Employers

To cover the cost of program administration, this proposed rule includes an administrative fee assessed on a per contract basis, paid by the tribal employer.[11] OPM has contracted with a paymaster to develop and maintain TIPS, an online portal for the input of enrollment data and transmission to carriers.

For fiscal year 2015, the administrative fee was $15.15 per contract; for fiscal year 2016 it is $12. This fee is adjusted to align with actual programmatic costs. As enrollment increases, this cost will go down as the costs of maintaining TIPS will be spread among more enrollments.

The cost of coverage for each tribal employer depends upon the number of enrollees covered, the health plans selected by those enrollees, and the portion of the premium paid by the employer.

Currently, the largest number of employees enrolled for one tribal employer is just under 4,000 and the smallest tribal employers have just one employee enrolled.[12] The majority of participating tribal employers have fewer than 150 employees enrolled, with a program-wide median of 71 enrolled employees.

The average cost per enrollment in the program, including the administrative fee, is estimated at approximately $10,172.[13]

Tribal employers are required by this rule to contribute to the premium for tribal employees at least the same as the Federal government does for its employees and may contribute more, up to 100% of the premium costs. The Federal government contribution is statutorily defined as the lesser of 72% of the weighted average of all premiums or 75% of the plan premium.[14] This averages out to approximately 70% paid by the employer, program-wide.

Based on averages for fiscal year 2015, a tribal employer may pay from just over $7,000 to over $40 million, depending on the number of tribal employees covered and percentage of premium contributed by the tribal employer. Of course, actual costs will vary based on plan selection.

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[5] Then Senator Barack Obama, Indian Health Care Improvement Act Amendments of 2007 Floor Speech, U.S. Senate, January 2008.

[6] The Federal Employees Health Plan Disparity Index (hereinafter "FDI") is an index comparing Indian Health Service (IHS) funding to the cost of providing medical insurance for American Indian/Alaska Native (AI/AN) users in a mainstream health insurance plan such as that offered under the Federal Employees Health Benefits Program (FEHBP). The FDI uses actuarial methods that control for age, sex, and health status to price health benefits for Indian people using the FEHBP, which is then used to make per capita health expenditure comparisons. See *http://www.nihb.org/docs/07112013/FY%202015%20IHS%20budget%20full%20report_FINAL.pdf* for 2010 information.

[7] This program was renamed in The Consolidated Appropriations Act of 2014 to the Purchased/Referred Care program. Discussion in this regulatory impact analysis provides pre-statutory examples covering 1992–2008 and cites the 2009 budget request. Although there is currently still major unmet need, funding for this program has increased from $579 million in FY 2008 to $914 million in FY 2016. See the FY17 Congressional Budget Justification at *https://www.ihs.gov/budgetformulation/includes/themes/newihstheme/documents/FY2017CongressionalJustification.pdf* for more up to date information.

[8] "The FY 2009 IHS Budget: Analysis and Recommendations," p. 22, March 17, 2008, available at: *www.npaihb.org.*

[9] This number does not include OPM's administrative costs to operate this program.

[10] The number of enrollments was multiplied by a family factor to estimate total covered lives including family members. The family factor is calculated for the FEHB Program as a whole, not based on actual tribal enrollment. The total annual cost was then divided by the total number of covered lives, the result of this was divided by 12 to estimate the cost per member per month.

[11] This is analogous with Federal agencies who cover the cost of program administration without an additional fee to employees.

[12] Based on September 2015 enrollment.

[13] Total annual cost (including administrative fee) divided by number of enrollees (using September 2015 data).

[14] 5 U.S.C. 8906.

Tribal employers assess the cost of participating and recognize that participation in the FEHB Program is a business decision made by the employers themselves. It often is a decision made by comparing the cost of other forms of health coverage and coverage through the FEHB Program. For those tribes that choose to participate it can be assumed that the benefits outweigh the costs of participation.

Costs for Tribal Employees

Costs for tribal employees depend upon the plan selected, enrollment type, and the percentage of premium contributed by the tribal employer. Based on FY15 data, the average cost for an annual enrollment is approximately $10,035 [15] with an average annual employee contribution of approximately $3,011. The actual tribal employee contribution varies based on the tribal employer contribution towards the premium.

Other costs such as copays, deductibles, and coinsurance are also the responsibility of the tribal employee, to the extent that such cost sharing is not otherwise prohibited by Federal law. These costs differ based on plan selection and utilization. Individual enrollment in the FEHB Program is voluntary so it can be assumed that the benefits to the individual of enrolling in tribal employer-sponsored coverage outweigh the costs of enrollment.

Administration of TIPS

Annual costs for administering TIPS, incurred by the paymaster, are described in the chart below. These costs are covered by the administrative fee paid by tribal employers.

Dates	Costs
May 2012 (launch date) through Sept 30, 2012	$1,096,932.00
2013 Fiscal year	1,677,293.68
2014 Fiscal year	1,653,397.93
2015 Fiscal year	1,815,660.00

Costs for OPM

Implementation of the Tribal FEHB Program began in fiscal year 2011. In addition to policy development and tribal consultation costs, OPM contracted with a paymaster to develop an electronic enrollment portal for tribal employers. Development of the Tribal Insurance Processing System (TIPS) cost approximately $3.9 million. OPM received approximately $3 million in funds from the Department of Health and Human Services' (HHS) Health Insurance Reform Implementation Fund and covered the remaining costs from funds appropriated to OPM.

OPM continues to incur costs associated with managing the Tribal FEHB Program. These costs are not covered by the administrative fee included in each tribal enrollment. See the chart below for Full Time Equivalent in FY2012–FY2015.

Fiscal year	FTE
FY2012	5.3
FY2013	3.5
FY2014	2.3
FY2015	1.8

FEHB Carriers

The impact on carriers is relatively small, as tribal enrollments are a very small percentage of the over 4 million FEHB enrollments. Premiums cover claims costs, administrative costs, plus a small profit known as the service charge.

Conclusion

While this rule meets the thresholds in Executive Orders 12866 and 13563 to be deemed an economically significant rule, many of the associated costs constitute transfers among involved parties. Under the provisions of this rule, participation in the FEHB Program is voluntary for both tribal employers and tribal employees. This, in conjunction with the relationship between costs incurred and the benefits of offering coverage, indicates that the benefits of this rule outweigh the costs.

List of Subjects on 5 CFR Part 890

Administrative practice and procedure, Government employees, Health insurance.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

For the reasons set forth in the preamble, OPM amends 5 CFR part 890 to read as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for Part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.303 also issued under Sec. 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; Subpart L also issued under Sec. 599C of Public Law 101–513, 104 Stat. 2064, as amended; Sec. 890.102 also issued under Secs. 11202(f), 11232(e), 11246(b) and (c) of Public Law 105–33, 111 Stat. 251; Sec. 721 of Public Law 105–261, 112 Stat. 2061 unless otherwise noted; Sec. 890.111 also issued under Sec. 1622(b) of Public Law 104–106, 110 Stat. 515. Subpart N issued under Sec. 10221, Pub. L. 111–148, 124 Stat 935 [25 U.S.C. 1647b].

■ 2. Add new subpart N to read as follows:

Subpart N—Federal Employees Health Benefits for Employees of Certain Indian Tribal Employers

Sec.
890.1401 Purpose.
890.1402 Definitions and deemed references.
890.1403 Tribal employer purchase of FEHB requires current deposit of payment.
890.1404 Tribal employer election and agreement to purchase FEHB.
890.1405 Tribal employees eligible for enrollment.
890.1406 Correction of enrollment errors.
890.1407 Enrollment process; effective dates.
890.1408 Change in enrollment type, plan, or option.
890.1409 Cancellation of coverage or decreases in enrollment.
890.1410 Termination of enrollment and 31-day temporary extension of coverage; and conversion to individual policy.
890.1411 Temporary Continuation of Coverage (TCC).
890.1412 Non-pay status, insufficient pay, or change to ineligible position.
890.1413 Premiums and administrative fee.
890.1414 Responsibilities of the tribal employer.
890.1415 Reconsideration of enrollment and eligibility decisions and appeal rights.
890.1416 Filing claims for payment or service and court review.
890.1417 No continuation of FEHB enrollment into retirement from employment with a tribal employer.
890.1418 No continuation of FEHB enrollment in compensationer status past 365 days.

Subpart N—Federal Employees Health Benefits for Employees of Certain Indian Tribal Employers

§ 890.1401 Purpose.

This subpart sets forth the conditions for coverage, rights, and benefits under Chapter 89 of title 5, United States Code, according to the provisions of 25 U.S.C. 1647b.

§ 890.1402 Definitions and deemed references.

(a) In this subpart—

Billing unit is a subdivision of the tribal employer's workforce that aligns tribal employees for purposes of administering FEHB enrollment and collection of payment. A billing unit may be either governmental or commercial or a combination of both. So long as a tribal employer purchases FEHB for at least one billing unit that is carrying out at least one program under ISDEAA or IHCIA, the tribal employer may purchase FEHB for other billing units without regard to its programs.

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[15] Does not include the Administrative Fee, which is covered by tribal employers.

Pay period is the interval of time for which a paycheck is issued by the tribal employer for work performed by the tribal employee.

Paymaster is the entity designated by OPM as responsible for receiving FEHB premiums from the tribal employer, forwarding premiums to the Employees Health Benefits Fund, and maintaining enrollment records for all participating tribal employers.

Payment is the sum of the tribal employer's share of premium plus the tribal employees' share of premium plus any administrative fees or costs required under this subpart, due for the enrollment, in the aggregate, of the tribal employer's tribal employees.

Tribal employee is a full-time or part-time common law employee of a tribal employer. An individual is a common law employee if, based on all the facts and circumstances, the tribal employer has the right to control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the details and means by which that result is accomplished. This determination is based on all facts and circumstances and shall be guided by the factors described by the Internal Revenue Service in Rev. Rul. 87–41, 1987–1 C.B. 296 and referenced in Joint Committee on Taxation report JCX–26–07 *Present Law and Background Relating to Worker Classification for Federal Tax Purposes,* dated May 7, 2007, and shall be consistent with the tribal employer's determination of common law employee status for Federal employment tax purposes, if any. For purposes of this subpart, tribal employees do not include retirees or annuitants of a tribal employer, volunteers of a tribal employer, or others who are not common law employees of a tribal employer. Categories of excluded tribal employees are described at § 890.1405(b). FEHB benefits available to tribal employees are set forth in this subpart and to the extent there exists any ambiguity or inconsistency between this subpart and other subparts of Part 890, the terms of this subpart will govern FEHB benefits available to tribal employees.

Tribal employer is an Indian tribe or tribal organization (as those terms are defined in 25 U.S.C. Chapter 18, "Indian Health Care") carrying out at least one program under the Indian Self-Determination and Education Assistance Act or an urban Indian organization (as that term is defined in 25 U.S.C. Chapter 18, "Indian Health Care") carrying out at least one program under the title V of the Indian Health Care Improvement Act, provided that the tribe, tribal organization, or urban Indian organization certifies entitlement to purchase FEHB according to the process described in subpart N. FEHB benefits that tribal employers are entitled to purchase for their tribal employees are set forth in this subpart and to the extent there exists any ambiguity or inconsistency between this subpart and other subparts of Part 890, the terms of this subpart will govern FEHB benefits available for purchase by tribal employers.

(b) In this subpart, wherever reference is made to other subparts of Part 890:

(1) A reference to employee is deemed a reference to tribal employee;

(2) A reference to employer is deemed a reference to tribal employer;

(3) A reference to enrollee is deemed a reference to a tribal employee in whose name the enrollment is carried;

(4) A reference to employing agency, employing office, or agency is deemed a reference to tribal employer, and/or if the reference involves the subject of a paymaster function, the paymaster, as appropriate;

(5) A reference to United States, Federal Government, or Government in the capacity of an employer is deemed a reference to tribal employer;

(6) A reference to Federal Service or Government Service is deemed a reference to employment with a tribal employer;

(7) A reference to annuitant, survivor annuitant, or an individual with entitlement to an annuity is deemed inapplicable in the context of this subpart; and

(8) A reference incorporated into this subpart that does not otherwise apply to tribal employees and tribal employers shall have no meaning and is deemed inapplicable in the context of this subpart.

§ 890.1403 Tribal employer purchase of FEHB requires current deposit of payment.

(a) A tribal employer shall be entitled to purchase coverage, rights, and benefits for its tribal employees under chapter 89 of title 5, United States Code, if payment for the coverage, rights, and benefits for the period of employment with such tribal employer is currently deposited in the Employees Health Benefits Fund.

(b) Payment will be considered currently deposited if received by the Employees Health Benefits Fund before, during, or within fourteen days after the end of the month covered by the payment.

(c) Purchase of FEHB coverage by a tribal employer confers all the rights and benefits of FEHB as set forth in subpart N to the tribal employer and tribal employee.

§ 890.1404 Tribal employer election and agreement to purchase FEHB.

(a) A tribal employer that intends to purchase FEHB for its tribal employees shall notify OPM by email or telephone.

(1) A tribal employer must purchase FEHB for at least one billing unit carrying out programs or activities under the tribal employer's ISDEAA or IHCIA contract.

(2) For so long as a tribal employer continues to purchase FEHB for at least one billing unit carrying out programs or activities under a tribal employer's ISDEAA or IHCIA contract, the tribal employer may purchase FEHB for one or more billing units without regard to whether they are carrying out programs or activities under the tribal employer's ISDEAA or IHCIA contract.

(b) A tribal employer must enter into an agreement with OPM to purchase FEHB. This agreement will include:

(1) The name, job title, and contact information of the individual responsible for health insurance coverage decisions for the tribal employer,

(2) The date on which the tribal employer will begin to purchase FEHB coverage,

(3) The approximate number of tribal employees who will be eligible to enroll,

(4) A certification that the eligible tribal employees within the enrolling billing unit will not have alternate tribal employer-sponsored health insurance coverage available concurrent with FEHB,

(5) A certification and documentation demonstrating that the tribal employer is entitled to purchase FEHB as either: An Indian tribe or tribal organization carrying out at least one program under the Indian Self-Determination and Education Assistance Act; or an urban Indian organization carrying out at least one program under Title V of the Indian Health Care Improvement Act,

(6) Agreement by the tribal employer that its purchase of FEHB makes the tribal employer responsible for administering the program in accordance with this subpart, subject to Federal Government audit with respect to such purchase and administration, and subject to OPM authority to direct the administration of the program, including but not limited to the correction of errors,

(7) Agreement that the tribal employer will establish or identify an independent dispute resolution panel to adjudicate appeals of determinations

made by a tribal employer regarding an individual's status as a tribal employee eligible to enroll in FEHB, eligibility of family members, and eligibility to change enrollment. This panel must have authority to enforce eligibility decisions,

(8) A certification that the tribal employer will supply necessary enrollment information and payment to the paymaster,

(9) Agreement to provide notice to OPM in the event that the tribal employer is no longer carrying out at least one program under the ISDEAA or title V of IHCIA, and

(10) Other terms and conditions as appropriate.

(c) A tribal employer may make an initial election to purchase FEHB at any time. A tribal employer purchasing FEHB shall commit to purchase FEHB for at least the remainder of the calendar year in which the agreement is signed. Elections will be automatically renewable year to year unless revoked by the tribal employer or terminated by OPM.

(d) If a tribal employer revokes the initial election, OPM must be given 60 days notice. The tribal employer may not re-elect to purchase FEHB until the first annual open season that falls at least twelve months after the revocation. If the tribal employer revokes an election to participate a second time, the tribal employer may not re-elect to purchase FEHB until the first open season that falls at least twenty-four months after the second revocation.

(e) OPM maintains final authority, in consultation with the United States Department of the Interior and the United States Department of Health and Human Services,to determine whether a tribal employer is entitled to purchase FEHB as either:

(1) An Indian tribe or tribal organization carrying out at least one program under the Indian Self-Determination and Education Assistance Act; or

(2) An urban Indian organization carrying out at least one program under Title V of the Indian Health Care Improvement Act. If a tribe, tribal organization or urban Indian organization believes it has been improperly denied the entitlement to purchase FEHB, it may appeal the denial to OPM. The appeal will be given an independent level of review within OPM and the decision on review will be final.

§ 890.1405 Tribal employees eligible for enrollment.

(a)(1) A tribal employee who is a full-time or part-time common law employee of a tribal employer is eligible to enroll in FEHB if that tribal employer has elected to purchase FEHB coverage for the tribal employees of that tribal employer's billing unit, except that a tribal employee described in paragraph (b) of this section is not eligible to enroll in FEHB.

(2) Status as a tribal employee under § 890.1402(a) for purposes of eligibility to enroll in FEHB is initially made based on a reasonable determination by the tribal employer. OPM maintains final authority to correct errors regarding FEHB enrollment as set forth at § 890.1406.

(3) Retirees, annuitants, volunteers, compensationers under Federal worker's disability programs past 365 days, and others who are not common law employees of the tribal employer are not eligible to enroll under this subpart.

(b) The following tribal employees are not eligible to enroll in FEHB:

(1) A tribal employee whose employment is limited to one year or less and who has not completed one year of continuous employment, including any break in service of 5 days or less;

(2) A tribal employee who is expected to work less than 6 months in one year;

(3) An intermittent tribal employee—a non-full-time tribal employee without a prearranged regular tour of duty;

(4) A beneficiary or patient employee in a Government or tribal hospital or home; and

(5) A tribal employee paid on a piecework basis, except one whose work schedule provides for full-time service or part-time service with a regular tour of duty.

(c) Notwithstanding paragraphs (b)(1), (2), and (3) of this section a tribal employee working on a temporary appointment, a tribal employee working on a seasonal schedule of less than 6 months in a year, or a tribal employee working on an intermittent schedule, for whom the tribal employer expects the total hours in pay status (including overtime hours) plus qualifying leave without pay hours to be at least 130 hours per calendar month, is eligible to enroll in FEHB according to terms described in § 890.102(j) unless the tribal employer provides written notification to the Director as described in § 890.102(k).

(d) The tribal employer initially determines eligibility of a tribal employee to enroll in FEHB, eligibility of family members, and eligibility of tribal employee to change enrollment. The tribal employer's initial decision may be appealed pursuant to § 890.1415.

(e) A tribal employee who is eligible and enrolls in FEHB under this subpart will have the option of enrolling in any FEHB open fee-for-service plan or health maintenance organization (HMO), consumer driven health plan (CDHP), or high deductible health plan (HDHP) available to Federal employees in the same geographic location as the tribal employee. The tribal employee will have the same choice of self only, self plus one, or self and family enrollment as is available to Federal employees.

(f) Family members of tribal employees will be covered by FEHB according to terms described at § 890.302. Children of tribal employees, whether married or not married, and whether or not dependent, are covered under a self and family enrollment or a self plus one enrollment (if the child is the designated covered family member) up to the age of 26. Former spouses of tribal employees are not former spouses as described at 5 U.S.C. 8901(10) and are not eligible to elect coverage under subpart H.

(g) Eligibility for FEHB under this subpart does not identify an individual as a Federal employee for any purpose, nor does it convey any additional rights or privileges of Federal employment.

§ 890.1406 Correction of enrollment errors.

Correction of errors regarding FEHB enrollment for tribal employees takes place according to the terms described in § 890.103.

§ 890.1407 Enrollment process; effective dates.

(a) *FEHB election for tribal employers.* Tribal employers may purchase FEHB coverage for their tribal employees after an agreement is accepted by OPM. Tribal employers will not be permitted to access FEHB if the tribal employer contributes toward an alternative employer-sponsored health insurance plan for tribal employees within the billing unit(s) for which the employer seeks to purchase FEHB coverage, with the exception of a collectively bargained alternative plan. A stand-alone dental, vision, or disability plan is not considered alternative health insurance.

(b) *Opportunities for tribal employees to enroll.* (1) Upon electing to purchase FEHB, a tribal employer will establish an initial enrollment opportunity for tribal employees. A tribal employee's enrollment upon an initial enrollment opportunity becomes effective as prescribed by OPM.

(2) After the initial enrollment opportunity, described in § 890.1407(b)(1), tribal employees are subject to the same initial enrollment

period, belated enrollment rules, enrollment by proxy, and open season as Federal employees, as described at § 890.301(a),(b),(c), and (f).

(3) A tribal employee who enrolls after the initial enrollment opportunity and who does not elect premium conversion through his or her tribal employer's premium conversion plan, if one is available, will be subject to the enrollment and qualifying life event rules described at § 890.301 and effective dates described at § 890.301(b) and (f).

(4) A tribal employee who enrolls after the initial enrollment opportunity and who elects premium conversion through his or her tribal employer's premium conversion plan, if one is available, will be subject to the enrollment rules, qualifying life event rules and effective dates described at §§ 892.207, 892.208 and 892.210 of this chapter (together with § 890.301 as referenced therein).

§ 890.1408 Change in enrollment type, plan, or option.

(a) A tribal employee enrolled under this subpart may increase or decrease his or her enrollment, or may change enrollment from one plan or option to another, as described in § 890.301 (for tribal employees who did not elect premium conversion) or Part 892 (for tribal employees who did elect premium conversion).

(b) A change in enrollment type, plan, or option under this section becomes effective as described in § 890.301 (for tribal employees who did not elect premium conversion) or Part 892 (for tribal employees who did elect premium conversion).

§ 890.1409 Cancellation of coverage or decreases in enrollment.

(a) A tribal employee enrolled under this subpart may cancel enrollment as described at § 890.304(d) or decrease his or her enrollment as described at § 890.301. A tribal employee who does not participate in premium conversion may cancel his or her enrollment or decrease his or her enrollment at any time by request to the tribal employer, unless there is a legally binding court or administrative order requiring coverage of a child as described at § 890.301(g)(3). A tribal employee who participates in premium conversion may cancel his or her enrollment as provided by § 892.209 or decrease his or her enrollment as provided by § 892.208 of this chapter only during open season or because of and consistent with a qualifying life event.

(b) A cancellation of enrollment becomes effective as described at § 890.304(d). A decrease in enrollment becomes effective as described in § 890.301(e)(2).

(c) A tribal employee who cancels his or her enrollment under this section or decreases his or her enrollment may reenroll or increase his or her enrollment only during open season or because of and consistent with a qualifying life event.

§ 890.1410 Termination of enrollment and 31-day temporary extension of coverage; and conversion to individual policy.

(a) *Tribal Employee Separation.* (1) Enrollment of a tribal employee under this subpart terminates due to separation from employment with the tribal employer for reasons of resignation, dismissal, or retirement. Termination of enrollment is effective at midnight of the last day of the pay period in which the tribal employee separates from employment.

(2) A former tribal employee who is separated under this subpart due to resignation, dismissal, or retirement and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(b) *Death of tribal employee.* (1) Enrollment of a tribal employee terminates at midnight of the last day of the pay period in which the tribal employee dies.

(2) If, at the time of death, the deceased tribal employee was enrolled in self and family FEHB coverage:

(i) The surviving spouse is entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401;

(ii) The covered children of the deceased tribal employee are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(3) If, at the time of death, the deceased tribal employee was enrolled in self plus one FEHB coverage, only the designated covered family member is entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(c) *Termination of family member coverage.* (1) Coverage of a family member of a tribal employee who was covered under this subpart terminates, subject to the 31-day temporary extension of coverage, for conversion, at midnight of the earlier of the following dates:

(i) The day on which he or she ceases to be a family member; or

(ii) The day the tribal employee's enrollment terminates, unless the family member is entitled to continued coverage under the enrollment of another.

(2) Family members who lose coverage under this subsection are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(d) *Tribal employer loses entitlement to purchase FEHB.* (1) Coverage of a tribal employee and family members under this subpart, except TCC that is already elected and in effect, terminates at midnight of the last day of the calendar year in which a tribal employer is no longer entitled to purchase FEHB. FEHB can terminate earlier at the request of the tribal employer.

(2) Following the termination described in § 890.1410(d)(1), enrolled tribal employees and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(e) *Tribal employer revokes election to purchase FEHB.* If a tribal employer voluntarily revokes its election to purchase FEHB, tribal employees will be entitled to a 31-day temporary extension of coverage and may convert to an individual policy as described at § 890.401. In such a case, the FEHB enrollment terminates effective the first day for which premium payment is not received and the 31-day temporary extension of coverage, for conversion begins immediately thereafter.

(f) *Failure to currently deposit payment.* (1) If payment is not currently deposited in the Employees Health Benefits Fund, the tribal employer's entitlement to purchase FEHB can be terminated, and all enrollments affected by the paymaster's failure to obtain current deposit of payment will be terminated, for non-payment.

(2) Enrollments of all of the tribal employer's tribal employees affected by the paymaster's failure to obtain current deposit of payment will be terminated effective midnight of the last day of the month for which payment was received.

(3) In the case of termination of enrollment due to non-payment, affected tribal employees will be entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401. The 31-day extension of

coverage begins immediately upon termination of enrollment.

(4) In the event that a tribal employer elects to purchase FEHB for its tribal employees but does not currently deposit payment in the first month that it is due, the enrollment of tribal employees affected by the paymaster's failure to obtain current deposit of payment will be terminated effective midnight of the last day of the month for which payment was not currently deposited. Tribal employees affected by the paymaster's failure to obtain current deposit of payment will not be entitled to a 31-day temporary extension of coverage and may not convert to an individual policy as described at § 890.401.

(5) Any outstanding premium due for coverage in arrears will be treated as a debt owed solely by the tribal employer.

§ 890.1411 Temporary Continuation of Coverage (TCC).

(a) For purposes of this subpart, temporary continuation of coverage (TCC) is described by 5 U.S.C. 8905a and subpart K. The administrative fee for TCC for tribal employees is the same as for Federal employees, with no specific tribal administrative fee as described in § 890.1413(e).

(b) A former tribal employee who is separated under this subpart due to resignation, dismissal, or retirement may elect TCC, unless the separation is due to gross misconduct as defined in § 890.1102.

(c) Eligibility for TCC for tribal employees following procedures provided in § 890.1103 of subpart K, except that former spouses of tribal employees are not eligible for TCC.

§ 890.1412 Non-pay status, insufficient pay, or change to ineligible position.

(a) *Non-pay status for 365 days.* Enrollment of a tribal employee and coverage of family members may continue for up to 365 days during which the tribal employee is in a non-pay status (as described at § 890.303(e)(1)) under terms described at § 890.502(b). Enrollment terminates at midnight of the last day of the pay period which includes the 365th consecutive day of nonpay status or the last day of leave under the Family and Medical Leave Act, whichever is later. The tribal employee and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(b) *Insufficient Pay.* If the pay of a non-temporary tribal employee who is enrolled in FEHB is insufficient to pay for the tribal employee's share of premiums, the tribal employer must follow the procedure described at § 890.502(b). If the enrollment is terminated due to insufficient pay, the tribal employee and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(c) *Insufficient Pay for temporary tribal employees.* If the pay of a temporary tribal employee who meets eligibility requirements described at 5 U.S.C. 8906a is insufficient to pay the tribal employee's share of premiums as described at § 890.304(a)(2), and the tribal employee does not or cannot elect a plan at a cost to him or her not in excess of the pay, the tribal employee's enrollment must be terminated as described at § 890.304(a)(2). The tribal employee and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(d) *Change to ineligible position.* A tribal employee who moves from an FEHB eligible to a non-FEHB-eligible position at a tribal employer will be eligible to continue FEHB enrollment as described in § 890.303(b).

(e) *Non-pay status due to Uniformed Service.* (1) Enrollment of a tribal employee and coverage of family members terminates at midnight of the earliest of the dates described at § 890.304(a)(1)(vi)–(viii). The tribal employee and covered family members are entitled to a 31-day temporary extension of coverage without premium contribution and may convert to an individual policy as described at § 890.401.

(2) Enrollment is reinstated on the date the tribal employee is restored to duty in an eligible position with the tribal employer upon return from Uniformed Service, pursuant to applicable law, provided that the tribal employer continues to purchase FEHB for its tribal employees in the affected tribal employee's billing unit on that date.

§ 890.1413 Premiums and administrative fee.

(a) Premium contributions and withholdings described at §§ 890.501 and 890.502 must be paid by the tribal employer and the tribal employee, except that the term OPM as used in § 890.502(c) is deemed to be a reference to the paymaster, as appropriate, for purposes of this subpart. There is no Government contribution as that term is used in 5 U.S.C 8906.

(b) *Contribution requirements.* (1)A tribal employer must contribute at least the monthly equivalent of the minimum Government contribution for a specific FEHB plan as described in 5 U.S.C. 8906;

(2) There is no cap on the percentage of premium that a tribal employer may contribute, as long as the contribution and withholding arrangement is not designed to encourage or discourage enrollment in any particular plan or plan option;

(3) A tribal employer may vary the contribution amount by type of FEHB enrollment (self only, self plus one, self and family), providing it is done in a uniform manner and meets the requirements described in § 890.1413(b)(1) and (2); and

(4) A tribal employer may vary the contribution amount by billing unit, providing each billing unit meets the requirements described in § 890.1413(b)(1)–(3).

(c) A tribal employer may, but is not required to, prorate the tribal employer and tribal employee share of premium attributable to enrollment of its part-time tribal employees working between 16 and 32 hours per week by prorating shares in proportion to the percentage of time that a tribal employee in a comparable full time position is regularly scheduled to work.

(d) Tribal employee and tribal employer contributions to premiums under this subpart will be aggregated by the tribal employer. The tribal employee and tribal employer contributions must be available for receipt by the paymaster on an agreed upon date. The paymaster will receive the premium contributions together with the fee described at paragraph (e) of this section and will deposit the payment into the Employees Health Benefits Fund described in 5 U.S.C. 8909.

(e) A fee determined annually by OPM will be charged in addition to premium for each enrollment of a tribal employee. The fee may be used for other purposes as determined by OPM. The fee must be paid entirely by the tribal employer as part of the payment to purchase FEHB for tribal employees, and must be available for collection by the paymaster, together with the aggregate tribal employee and tribal employer contributions, in time to be currently deposited into the Employees Health Benefits Fund described in 5 U.S.C. 8909.

§ 890.1414 Responsibilities of the tribal employer.

(a) The tribal employer pays premiums for tribal employees enrolled under this subpart pursuant to §§ 890.1403 and 890.1413.

(b) The tribal employer must determine the eligibility of individuals who attempt to enroll for coverage under this subpart and enroll those it finds eligible.

(c) The tribal employer must determine whether eligible tribal employees have eligible family member(s) and allow coverage under a self plus one or self and family enrollment as described in § 890.302 for those it finds eligible.

(d) The tribal employer must establish or identify an independent dispute resolution panel for reconsideration of enrollment and eligibility decisions as described in § 890.1415.

(e) The tribal employer has the following notification responsibilities. The tribal employer must:

(1) Notify OPM and tribal employees in writing of intent to revoke election to purchase FEHB at least 60 days before such revocation described at § 890.1404(d);

(2) Promptly notify tribal employees and OPM if there is a change in the tribal employer's entitlement to purchase FEHB described at § 890.1410(d);

(3) Promptly notify affected tribal employees of termination of enrollment due to non-payment, the 31-day temporary extension of coverage and its ending date described at § 890.1410(f)(2)–(3); and

(4) Promptly notify affected tribal employees of termination of enrollment due to non-payment described at § 890.1410(f)(4).

§ 890.1415 Reconsideration of enrollment and eligibility decisions and appeal rights.

(a) The tribal employer shall establish or identify an independent dispute resolution panel to adjudicate appeals of determinations made by a tribal employer denying an individual's status as a tribal employee eligible to enroll in FEHB or denying a change in the type of enrollment (*i.e.,* to or from self only coverage) under this subpart. Such panel shall be authorized to enforce enrollment and eligibility decisions. The tribal employer shall notify affected individuals of this panel and its functions.

(b) Under procedures set forth by the tribal employer, an individual may file a written request to the independent dispute resolution panel to reconsider an initial decision of the tribal employer under this subpart. A reconsideration decision made by the panel must be issued to the individual in writing and must fully state the findings and reasons for the findings. The panel may consider information from the tribal employer, the individual, or another source. The panel must retain a file of its documentation until December 31 of the 3rd year after the year in which the decision was made, and must provide the file to OPM upon request.

(c) If the panel determines that the individual is ineligible to enroll in FEHB as a tribal employee or to change enrollment, the individual may request that OPM reconsider the denial. Such a request must be made in writing and any decision by OPM will be binding on the tribal employer.

(d) OPM may request a panel decision file during the retention period described at paragraph (b) of this section. Panel decisions remain subject to final OPM authority to correct errors, as set forth in § 890.1406.

§ 890.1416 Filing claims for payment or service and court review.

(a) Tribal employees may file claims for payment or service as described at § 890.105.

(b) Tribal employees may invoke the provisions for court review described at § 890.107(b)–(d).

§ 890.1417 No continuation of FEHB enrollment into retirement from employment with a tribal employer.

(a) An FEHB enrollment cannot be continued into retirement from employment with a tribal employer.

(b) A Federal annuitant may continue FEHB enrollment into retirement from Federal service if the requirements of 5 U.S.C. 8905(b) for carrying FEHB coverage into retirement are satisfied through enrollment, or coverage as a family member, either through a Federal employing office or a tribal employer, or any combination thereof.

(c) A Federal annuitant who is employed after retirement by a tribal employer in an FEHB eligible position may participate in FEHB through the tribal employer. In such a case, the Federal annuitant's retirement system will transfer the FEHB enrollment to the tribal employer, in a similar manner as for a Federal annuitant who is employed by a Federal agency after retirement.

(d) A tribal employee who becomes a survivor annuitant as described in 890.303(d)(2) is entitled to reinstatement of health benefits coverage as a Federal employee would under the same circumstances.

§ 890.1418 No continuation of FEHB enrollment in compensationer status past 365 days.

A tribal employee who is not also a Federal employee who becomes eligible for one of the Department of Labor's disability compensation programs may not continue FEHB coverage in leave without pay status past 365 days.

[FR Doc. 2016–20566 Filed 8–30–16; 8:45 am]

BILLING CODE 6325–63–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–7003; Directorate Identifier 2016–CE–015–AD]

RIN 2120–AA64

Airworthiness Directives; PILATUS AIRCRAFT LTD. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of the comment period.

SUMMARY: We are revising an earlier NPRM for all PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes that would supersede AD 2014–22–01. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a need to incorporate new revisions into the Limitations section, Chapter 4, of the FAA-approved maintenance program (*e.g.,* maintenance manual). We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by October 17, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal*: Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE.,

Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact PILATUS AIRCRAFT LTD., Customer Service Manager, CH–6371 STANS, Switzerland; telephone: +41 (0) 41 619 33 33; fax: +41 (0) 41 619 73 11; Internet: *http://www.pilatus-aircraft.com* or email: *SupportPC12@pilatus-aircraft.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7003; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–7003; Directorate Identifier 2016–CE–015–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We proposed to amend 14 CFR part 39 with an NPRM for all PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes that would supersede AD 2014–22–01, which was published in the **Federal Register** on June 8, 2016 (81 FR 36810). The NPRM proposed to require actions intended to address the unsafe condition for the products listed above and was based on mandatory continuing airworthiness information (MCAI) originated by another country. The MCAI states:

> The airworthiness limitations are currently defined and published in the Pilatus PC–12 Aircraft Maintenance Manual(s) (AMM) under Chapter 4, Structural, Component and Miscellaneous—Airworthiness Limitations Section (ALS) documents. The limitations contained in these documents have been identified as mandatory for continued airworthiness.
>
> Failure to comply with these instructions could result in an unsafe condition.
>
> EASA issued AD 2014–0170 requiring the actions as specified in ALS, Chapter 4 of AMM report 02049 issue 28, for PC–12, PC–12/45 and PC–12/47 aeroplanes, and Chapter 4 of AMM report 02300 issue 11, for PC–12/47E aeroplanes.
>
> Since that AD was issued, Pilatus issued Chapter 4 of PC–12 AMM report 02049 issue 31, and Chapter 4 of PC–12 AMM report 02300 issue 14 (hereafter collectively referred to as 'the applicable ALS' in this AD), to incorporate new six-year and ten-year inspection intervals for several main landing gear (MLG) attachment bolts, and an annual inspection interval for the MLG shock absorber attachment bolts, which was previously included in the AMM Chapter 5 annual inspection. After a further review of the in-service data, Pilatus issued Service Letter (SL) 186, extending the special compliance time applicable for the MLG bolts inspection.
>
> For the reasons described above, this AD retains the requirements of EASA AD 2014–0170, which is superseded, and requires the accomplishment of the new maintenance tasks, as described in the applicable ALS.

The MCAI can be found in the AD docket on the Internet at *https://www.regulations.gov/document?D=FAA-2016-7003-0002.*

Since the NPRM was issued, PILATUS AIRCRAFT LTD. has issued new revisions to the Limitations section, Chapter 4, to be incorporated into the FAA-approved maintenance program (*e.g.,* maintenance manual).

Related Service Information Under 1 CFR Part 51

PILATUS AIRCRAFT LTD. has issued Structural, Component and Miscellaneous—Airworthiness Limitations, document 12–A–04–00–00–00A–000A–A, dated July 12, 2016, and Structural and Component Limitations—Airworthiness Limitations, document 12–B–04–00–00–00A–000A–A, dated July 19, 2016. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this supplemental NPRM.

Comments

We have considered the following comments received on the NPRM.

Request To Incorporate Newly Issued Revisions to the Limitations Section, Chapter 4, of the FAA-Approved Maintenance Program (*e.g.,* Maintenance Manual)

Johan Kruger of Pilatus Aircraft requested incorporating a newly issued revision of the Limitation section, Chapter 4, of each applicable maintenace manual into the proposed AD.

Johan Kruger of Pilatus Aircraft stated that in the Aircraft Maintenance Manual (AMM) Airworthines Limitations Section (ALS) 12–A–04–00–00–00A–000A–A, the Supplemental Structural Inspection Document (SSID) part has been updated with kit numbers and brought in line with Service Bulletin (SB) SB 04–009. The commenter stated that the changes were coordinated with the FAA, who concurred that no new limitations are incorporated in the ALS. The AMM/ALS 12–B–04–00–00–00A–000A–A has also been updated by introducing an inspection of the passenger oxygen (drop down mask) system if installed, and this change was also coordinated with the FAA. Since the drop down O2 system is only required by European operation requirements and not currently earmarked for the United States, it is also not introducing new limitations for U.S. operators.

We agree with the commenter and have changed this supplemental NPRM based on this comment.

Request To Change the Compliance Times for Inspecting the Main Landing Gear (MLG) Attachment Bolts

Johan Kruger of Pilatus Aircraft and Blake Morley of Aero Air, LLC requested changing the compliance time for inspecting the main landing gear (MLG) attachment bolts. The commenters stated that the compliance time in the proposed AD is causing confusion because the way it is currently stated, which is "within the next 6 years . . . or within the next 3 months . . . whichever occurs later," does not makes sense because 6 years will always occur later and it goes against what is specified in the revisions to the ALS that is being incorporated by this proposed AD.

Johan Kruger of Pilatus Aircraft stated that, in the ALS Notes, Note 1 (ALS 12–B–04) and Note 3 (ALS 12–A–04) respectively, the inspection is to be done by a specific date, and he wants those dates incorporated into this proposed AD. Blake Morley of Aeroa Air, LLC stated that EASA has also adopted the grace period extension in EASA AD 2016–0083, stating: "Note 1: For the purpose of this AD, the thresholds and intervals include 'special' compliance times for certain tasks as defined in the applicable ALS, and the 'special' compliance time for the inspection of MLG bolts, as defined in SL 186." Blake Morley also requested the "3-month" grace period compliance time be changed to "before December 31, 2016."

We partially agree with the commenters. We do agree that the compliance times for the inspection of the MLG attachment bolts needs to be corrected to reflect before or upon the accumulation of time-in-service (TIS) on the MLG attachment bolts instead of the TIS on the airplane, which then makes the 3-month grace period more applicable. We have changed this supplemental NPRM action based on this portion of the comment.

We do not agree with using a specific date as a compliance time. There is no correlation with the requested dates and the unsafe condition. The mere fact that the service document or an international civil aviation authority's AD refers to a calendar date is not enough to justify using a calendar date in a U.S. AD. We have not changed this supplemental NPRM action based on this portion of the comment.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this supplemental NPRM.

Costs of Compliance

We estimate that this proposed AD will affect 770 products of U.S. registry. We also estimate that it would take about 1.5 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $98,175, or $127.50 per product. This breaks down as follows:

- Incorporating new revisions into the Limitations section, Chapter 4, of the FAA-approved maintenance program (*e.g.,* maintenance manual): .5 work-hour for a fleet cost of $32,725, or $42.50 per product.
- New inspections of the MLG attachment bolts: 1 work-hour with no parts cost for fleet cost of $65,450 or $85 per product.

In addition, we estimate that any necessary corrective actions (on-condition costs) that must be taken based on the proposed inspections, would take about 1 work-hour and require parts costing approximately $100 for a cost of $185 per product. We have no way of determining the number of products that may need these necessary corrective actions.

The only costs that would be imposed by this proposed AD over that already required by AD 2014–22–01 is the costs associated with the insertion of the revised Limitation section and the MLG attachment bolts inspection and replacement as necessary.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

PILATUS AIRCRAFT LTD.: Docket No. FAA–2016–7003; Directorate Identifier 2016–CE–015–AD.

(a) Comments Due Date

We must receive comments by October 17, 2016.

(b) Affected ADs

This AD replaces AD 2014–22–01, 39–18005 (79 FR 67343, November 13, 2014).

(c) Applicability

This AD applies to PILATUS AIRCRAFT LTD. Models PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes, all manufacturer serial numbers (MSNs), certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 5: Time Limits.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a need to incorporate new revisions into the Limitations section, Chapter 4, of the FAA-approved maintenance program (*e.g.*, maintenance manual). The limitations were revised to include repetitive inspections of the main landing gear (MLG) attachment bolts. These actions are required to ensure the continued operational safety of the affected airplanes.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (6) of this AD:

(1) Before further flight after October 5, 2016 (the effective date of this AD), insert the following revisions into the Limitations section of the FAA-approved maintenance program (*e.g.*, maintenance manual):

(i) STRUCTURAL, COMPONENT AND MISCELLANEOUS—AIRWORTHINESS LIMITATIONS, Data module code 12–A–04–00–00–00A–000A–A, dated July 12, 2016, of the Pilatus Model type—PC–12, PC–12/45, PC–12/47, Aircraft Maintenance Manual (AMM), Document No. 02049, 12–A–AM–00–00–00–I, revision 32, dated July 18, 2016; and

(ii) STRUCTURAL AND COMPONENT LIMITATIONS—AIRWORTHINESS LIMITATIONS, Data module code 12–B–04–00–00–00A–000A–A, dated July 19, 2016, of the Pilatus Model type—PC–12/47E MSN–1001–UP, Aircraft Maintenance Manual (AMM), Document No. 02300, 12–B–AM–00–00–00–I, revision 15, dated July 30, 2016.

(2) The new limitations section revisions listed in paragraphs (f)(1)(i) and (ii) of this AD specify the following:

(i) Establish inspections of the MLG attachment bolts,

(ii) Specify replacement of components before or upon reaching the applicable life limit, and

(iii) Specify accomplishment of all applicable maintenance tasks within certain thresholds and intervals.

(3) Only authorized Pilatus Service Centers can do the Supplemental Structural Inspection Document (SSID) as required by the documents in paragraphs (f)(1)(i) and (ii) of this AD because deviations from the type design in critical locations could make the airplane ineligible for this life extension.

(4) If no compliance time is specified in the documents listed in paragraphs (f)(1)(i) and (ii) of this AD when doing any corrective actions where discrepancies are found as required in paragraph (f)(2)(iii) of this AD, do these corrective actions before further flight after doing the applicable maintenance task.

(5) During the accomplishment of the actions required in paragraph (f)(2) of this AD, including all subparagraphs, if a discrepancy is found that is not identified in the documents listed in paragraphs (f)(1)(i) and (ii) of this AD, before further flight after finding the discrepancy, contact PILATUS AIRCRAFT LTD. at the address specified in paragraph (h) of this AD for a repair scheme and incorporate that repair scheme.

(6) Before or upon accumulating 6 years time-in-service (TIS) on the MLG attachment bolts or within the next 3 months TIS after October 5, 2016 (the effective date of this AD), whichever occurs later, inspect the MLB attachment bolts for cracks and corrosion and before further flight take all necessary corrective actions.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov*.

(i) Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(ii) AMOCs approved for AD 2014–22–01, 39–18005 (79 FR 67343, November 13, 2014) are not approved as AMOCs for this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2016–0083, dated April 28, 2016, for related information. You may examine the MCAI on the Internet at *https://www.regulations.gov/document?D=FAA-2016-7003-0002*. For service information related to this AD, contact PILATUS AIRCRAFT LTD., Customer Service Manager, CH–6371 STANS, Switzerland; telephone: +41 (0) 41 619 33 33; fax: +41 (0) 41 619 73 11; Internet: *http://www.pilatus-aircraft.com* or email: *SupportPC12@pilatus-aircraft.com*. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on August 23, 2016.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20828 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8851; Directorate Identifier 2016–NM–070–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A330–200 Freighter, –200, and –300 series airplanes; and Airbus Model A340–500, and –600 series airplanes. This proposed AD was prompted by reports that non-conforming aluminum alloy was used to manufacture several structural parts on the inboard flap. This proposed AD would require identification of the potentially affected inboard flap parts, a one-time eddy current inspection to identify which material the parts are made of, and depending on findings, replacement with serviceable parts. We are proposing this AD to detect and correct structural parts of inboard flaps made of nonconforming aluminum alloy, which could result in reduced structural integrity of the airplane.

DATES: We must receive comments on this proposed AD by October 17, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com*; Internet: *http://www.airbus.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue

SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8851; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1138; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–8851; Directorate Identifier 2016–NM–070–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2016–0082, dated April 27, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition all Airbus Model A330–200 Freighter, –200, and –300 series airplanes; and Airbus Model A340–500, and –600 series airplanes. The MCAI states:

> Following an Airbus quality control review on the final assembly line, it was discovered that non-conforming aluminium alloy was used to manufacture several structural parts on the inboard flap.
>
> This condition, if not detected and corrected, could reduce the structural integrity of the aeroplane.
>
> To address this potential unsafe condition, Airbus issued Service Bulletin (SB) A330–57–3120 and SB A340–57–5036 to provide instructions to identify and inspect the potentially affected parts.
>
> For the reasons described above, this [EASA] AD requires identification of the potentially affected inboard flap parts, a one-time Special Detailed Inspection (SDI) [eddy current measurement] to identify which material they are made of and, depending on findings, replacement with serviceable parts.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8851.

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Service Bulletin A330–57–3120, dated September 18, 2015; and Airbus Service Bulletin A340–57–5036, dated September 18, 2015. The service information describes procedures for inspecting inboard flaps using eddy current inspection methods. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 31 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	5 work-hours × $85 per hour = $425	$0	$425	$13,175

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of airplanes that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Remove and Replace Flap	60 work-hours × $85 per hour = $5,100	Unavailable	$5,100

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. The cost of purchasing a flap spare is not available. As a result, we have included only labor costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2016–8851; Directorate Identifier 2016–NM–070–AD.

(a) Comments Due Date

We must receive comments by October 17, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A330–223F and –243F airplanes; A330–201, –202, –203, –223, and –243 airplanes; A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; A340–541 airplanes; and A340–642 airplanes; certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by reports that nonconforming aluminum alloy was used to manufacture several structural parts on the inboard flap. We are issuing this AD to detect and correct structural parts of inboard flaps made of nonconforming aluminum alloy, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inboard Flap Serial Number Identification

Within 24 months after the effective date of this AD: Inspect each left-hand (LH) and right-hand (RH) inboard flap, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3120, dated September 18, 2015; and Airbus Service Bulletin A340–57–5036, dated September 18, 2015; as applicable; to identify the serial number. A review of airplane delivery and maintenance records is acceptable in lieu of inspecting the inboard flaps, provided those records can be relied upon for that purpose and the serial number of the affected parts can be conclusively identified from that review. The serial numbers of affected inboard flaps are identified in figure 1 to paragraph (g) of this AD.

Note 1 to paragraphs (g) and (h) of this AD: Airbus Service Bulletin A330–57–3120, dated September 18, 2015; and Airbus Service Bulletin A340–57–5036, dated September 18, 2015; list the serial numbers of potentially affected LH and RH inboard flaps and the corresponding airplane serial number on which these parts were installed during production. The airplane serial number list is for information only, as it cannot be excluded that a potentially affected inboard flap has been removed from an airplane and later re-installed on another airplane.

Figure 1 to Paragraph (g) of This AD—Affected Flap Serial Numbers (s/n)

Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n
29/09/10	11004	11004	28/02/11	11202	11201	19/12/12	11349	11349
21/07/09	11030	11028	22/02/11	11198	11202	17/12/12	11352	11352
17/08/09	11034	11002	07/03/11	11203	11203	15/11/12	11353	11353
21/05/10	11031	11031	30/03/11	11204	11204	30/10/12	11354	11354
09/08/10	11071	11071	31/05/11	11205	11229	22/10/12	11355	11355
10/07/09	11033	11057	15/03/11	11206	11206	31/10/12	11383	11357
06/08/10	11036	11098	24/03/11	11208	11208	30/10/12	11380	11356
29/07/09	11035	11035	04/04/11	11209	11209	26/11/12	11359	11393
19/08/09	11057	11036	22/03/11	11210	11210	30/11/12	11361	11361
23/12/09	11037	11033	23/03/11	11211	11213	16/11/12	11358	11358
14/09/09	11038	11038	24/03/11	11212	11212	30/11/12	11325	11360
17/09/10	11042	11039	14/04/11	11213	11214	12/12/12	11399	11365
23/09/09	11040	11040	14/04/11	11229	11215	26/11/12	11362	11362
11/09/09	11041	11041	11/04/11	11215	11217	09/11/12	11363	11363
12/05/10	11046	11042	06/04/11	11216	11216	30/11/12	11364	11364
01/10/09	11043	11043	12/04/11	11217	11219	23/11/12	11365	11368
01/10/09	11044	11044	15/04/11	11218	11218	07/12/12	11366	11366
08/09/09	11047	11045	04/05/11	11219	11221	06/12/12	11367	11367
07/09/09	11049	11046	29/04/11	11220	11220	19/12/12	11368	11370
18/09/09	1970	11047	11/05/11	11238	11222	11/12/12	11369	11369

FIGURE 1 TO PARAGRAPH (g) OF THIS AD—AFFECTED FLAP SERIAL NUMBERS (S/N)—Continued

Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n
30/09/09	11048	11048	13/05/11	11222	11223	21/12/12	11370	11372
26/10/09	11055	11049	06/05/11	11223	11224	13/12/12	11372	11375
03/09/10	11051	11051	19/05/11	11224	11225	20/12/12	11373	11373
30/10/09	11054	11054	19/05/11	11225	11205	21/12/12	11374	11374
19/11/09	11053	11053	29/06/11	11226	11226	16/01/13	11375	11377
28/10/10	11008	11019	25/05/11	11227	11227	11/01/13	11376	11376
27/10/09	11015	11055	16/05/11	11228	11228	15/01/13	11377	11350
28/10/09	11059	11059	10/06/11	11092	11092	05/02/13	11378	11381
29/10/09	11060	11060	23/11/11	11231	11231	25/01/13	11379	11379
16/11/10	11063	11063	08/07/11	11232	11232	18/01/13	11382	11380
23/12/09	11061	11061	23/06/11	11234	11234	22/03/13	11381	11382
23/11/09	11066	11066	22/06/11	11233	11233	27/02/13	11371	11371
03/11/10	11070	11070	24/06/11	11237	11237	08/03/13	11385	11383
30/11/09	11065	11065	15/06/11	11235	11235	06/02/13	11384	11384
30/11/09	11032	11032	01/07/11	11236	11236	05/02/13	11386	11385
18/11/09	11067	11067	12/07/11	11239	11239	19/02/13	11406	11389
17/12/09	11072	11072	25/11/11	11115	11115	16/03/13	11387	11387
24/11/09	11074	11074	29/07/11	11240	11240	25/02/13	11388	11388
17/09/10	11147	11147	06/10/11	11243	11243	15/02/13	11390	11390
23/12/09	11095	11095	29/07/11	11244	11241	25/02/13	11392	11392
10/12/09	11075	11075	03/08/11	11245	11245	01/03/13	11391	11403
07/12/09	11076	11076	29/08/11	11246	11244	01/03/13	11394	11394
23/12/09	11077	11077	22/08/11	11247	11247	11/03/13	11393	11395
22/12/09	11069	11069	20/12/11	11248	11246	08/03/13	11397	11397
07/12/09	11079	11079	30/08/11	11249	11249	14/03/13	11395	11399
19/01/10	11078	11078	25/08/11	11136	11248	18/03/13	11396	11396
11/02/10	11081	11081	06/09/11	11250	11250	18/03/13	11356	11400
26/03/10	11080	11080	27/09/11	11252	11254	28/03/13	11398	11398
28/01/10	11082	11082	28/09/11	11221	11251	22/03/13	11401	11401
28/01/10	11084	11084	15/09/11	11214	11255	09/04/13	11400	11402
04/02/10	11098	11030	20/10/11	11266	11256	21/03/13	11404	11404
29/01/10	11085	11085	19/12/11	11258	11258	09/04/13	11402	11405
05/02/10	11039	11037	19/10/11	11255	11259	26/04/13	11403	11407
29/03/10	11086	11086	10/11/11	11259	11260	15/04/13	11360	11406
09/03/10	11087	11087	05/10/11	11261	11261	11/04/13	11407	11408
15/04/10	11088	11088	17/10/11	11260	11263	19/04/13	11409	11409
16/04/10	11089	11089	10/11/11	11254	11252	24/04/13	11410	11410
29/03/10	11090	11090	17/11/11	11262	11262	19/04/13	11411	14411
11/06/10	11091	11091	16/11/11	11263	11264	22/04/13	11408	11412
22/06/11	11230	11230	16/11/11	11264	11265	26/04/13	11413	11413
23/03/10	11093	11093	25/11/11	11265	11266	30/04/13	11414	11414
23/02/10	11094	11094	28/11/11	11267	11267	22/04/13	11412	11415
24/03/10	11073	11073	05/12/11	11268	11268	15/07/13	11416	11416
31/03/10	11096	11096	29/11/11	11270	11270	17/05/13	11405	11417
16/03/10	11097	11097	06/12/11	11271	11271	28/05/13	11415	11418
10/03/10	11101	11101	12/12/11	11272	11272	23/05/13	11419	11419
15/03/10	11099	11099	07/12/11	11275	11275	17/05/13	11417	11421
23/03/10	11100	11100	14/12/11	11269	11269	30/05/13	11418	11420
16/06/10	11105	11105	15/12/11	11274	11274	30/05/13	11357	11386
07/12/10	11102	11130	12/12/11	11276	11276	27/05/13	11420	11422
13/04/10	11106	11106	11/01/12	11279	11279	13/06/13	11421	11423
27/04/10	11104	11104	20/01/12	11278	11278	04/06/13	11424	11424
30/04/10	11103	11103	19/01/12	11164	11164	17/06/13	11426	11378
07/04/10	11108	11108	12/01/12	11277	11277	10/06/13	11423	11427
16/04/10	11133	11133	19/01/12	11280	11281	27/06/13	11428	11428
10/05/10	11114	11114	23/01/12	11298	11282	20/06/13	11425	11425
10/05/10	11110	11110	17/01/12	11282	11284	27/06/13	11429	11426
06/05/10	11116	11116	30/01/12	11283	11283	21/06/13	11427	11429
27/05/10	11112	11112	01/02/12	11284	11285	01/07/13	11434	11434
13/07/11	11241	11238	24/02/12	11286	11286	01/07/13	11432	11432
11/05/10	11111	11034	17/02/12	11285	11287	23/07/13	11430	11430
17/06/10	11118	11118	29/02/12	11287	11289	31/07/13	11431	11431
09/06/10	11120	11120	22/02/12	11288	11288	19/07/13	11436	11436
16/07/10	11122	11122	23/02/12	11289	11291	12/07/13	11433	11433
06/07/10	11123	11123	24/02/12	11290	11290	01/08/13	11437	11437
21/05/10	11124	11124	21/02/12	11291	11293	15/07/13	11435	11435
12/07/10	11126	11126	04/04/12	11292	11292	19/07/13	11438	11316
28/06/10	11127	11127	05/04/12	11293	11294	13/11/13	11440	11438
18/06/10	11129	11129	20/03/12	11294	11296	06/08/13	11441	11441
22/06/10	11130	11102	09/03/12	11295	11295	02/08/13	11439	11439
24/09/10	11135	11135	30/03/12	11296	11298	05/08/13	11442	11440

FIGURE 1 TO PARAGRAPH (g) OF THIS AD—AFFECTED FLAP SERIAL NUMBERS (S/N)—Continued

Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n	Date of first operation	LH s/n	RH s/n
25/06/10	11132	11132	29/03/12	11297	11297	09/08/13	11443	11391
26/07/10	E11006	11111	16/03/12	11299	11175	27/08/13	11446	11442
23/07/10	11138	11138	29/03/12	11300	11300	19/08/13	11447	11443
14/09/11	11251	11136	18/04/12	11281	11301	04/09/13	11444	11444
15/07/10	11062	11062	12/04/12	11302	11180	03/09/13	11445	11445
23/07/10	11141	11141	26/04/12	11301	11303	25/09/13	11449	11446
23/08/10	11145	11145	20/04/12	11303	11306	13/09/13	11450	11447
27/08/10	11117	11117	24/04/12	11304	11307	29/10/13	11448	11448
13/08/10	11146	11146	27/04/12	11305	11305	26/09/13	11453	11449
13/09/10	11149	11149	25/04/12	11306	11308	02/12/13	11454	11450
27/09/10	11150	11150	26/04/12	11307	11196	25/09/13	11451	11451
14/11/11	11148	11148	14/05/12	11308	11310	25/09/13	11472	11464
17/09/10	11151	11151	10/05/12	11310	11312	27/09/13	11457	11453
28/09/10	11107	11107	11/05/12	11312	11317	28/10/13	11458	11454
27/09/10	11159	11159	09/05/12	11309	11299	22/10/13	11456	11455
25/10/10	11153	11153	25/05/12	11311	11311	11/10/13	11455	11456
29/09/10	11155	11155	29/05/12	11313	11313	25/10/13	11459	11459
08/10/10	11156	11156	31/05/12	11314	11314	20/11/13	11460	11458
13/10/10	11157	11157	28/06/12	11317	11315	17/10/13	11461	11461
15/10/10	11168	11168	15/06/12	11316	11336	21/10/13	11462	11460
13/10/10	11186	11160	15/06/12	11318	11318	23/10/13	11463	11463
22/10/10	11161	11161	31/05/12	11319	11319	05/11/13	11465	11462
22/10/10	11163	11163	18/06/12	11320	11320	04/11/13	11466	11466
25/01/12	11256	11280	22/06/12	11321	11321	13/11/13	11452	11473
22/11/10	11165	11165	19/07/12	11322	11322	04/11/13	11389	11465
10/11/10	11167	11167	29/06/12	11323	11323	22/11/13	11468	11457
02/12/10	1960	1960	11/07/12	11324	11324	27/11/13	11467	11467
15/11/10	11169	11169	26/06/12	11348	11325	11/12/13	11470	11468
30/11/10	11178	11170	09/07/12	11326	11326	18/11/13	11469	11469
10/11/10	11171	11171	03/07/12	11327	11327	02/12/13	11474	11470
30/11/10	11183	11172	12/07/12	11328	11328	02/12/13	11471	11471
26/11/10	11173	11173	16/07/12	11329	11329	30/12/13	11503	11488
14/12/10	11174	11174	24/08/12	11330	11330	16/12/13	11476	11474
15/06/12	11175	11302	13/07/12	11331	11331	16/12/13	11477	11477
19/11/10	11177	11177	23/07/12	11332	11332	06/12/13	11475	11475
23/12/10	11172	11178	29/08/12	11333	11333	03/12/13	11479	11476
11/04/12	11315	11304	10/08/12	11334	11334	09/12/13	11480	11480
16/12/10	11181	11181	23/07/12	11335	11335	09/12/13	11478	11489
15/12/10	11184	11183	30/08/12	11337	11337	09/12/13	11481	11481
15/12/10	11187	11184	30/07/12	11336	11309	17/12/13	11482	11482
14/01/11	11188	11188	31/08/12	11180	11339	09/01/14	11483	11483
25/01/11	11189	11187	18/09/12	11340	11340	21/01/14	11484	11484
21/01/11	11160	11189	30/11/12	11339	11341	27/02/14	11486	11486
12/01/11	11190	11190	12/09/12	11341	11343	27/01/14	11487	11487
25/01/11	11192	11186	15/10/12	11343	11345	17/01/14	11485	11485
07/02/11	11191	11191	17/09/12	11346	11347	31/01/14	11489	11490
07/02/11	11193	11192	28/09/12	11345	11344	14/01/14	11490	11491
18/02/11	11195	11193	09/10/12	11342	11342	29/01/14	11488	11492
24/02/11	11196	11195	24/09/12	11344	11346	30/01/14	11492	11493
25/02/11	11199	11211	15/10/12	11347	9015	24/01/14	11493	11479
25/02/11	11200	11198	21/09/12	11338	11348	27/02/14	11491	11494
21/02/11	11201	11199	19/10/12	11350	11359	16/06/14	11495	11495
14/02/11	11170	11200	17/10/12	11351	11351	14/02/14	11498	11498

(h) Eddy Current Conductivity Measurement

For each affected inboard flap, within 6 years after the effective date of this AD, or within 12 years after the date of the flap first operation, whichever occurs first, accomplish an eddy current conductivity measurement, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3120, dated September 18, 2015; or Airbus Service Bulletin A340–57–5036, dated September 18, 2015; as applicable.

Note 2 to paragraph (h) of this AD: The date of first operation is shown in figure 1 to paragraph (g) of this AD as day, month, year (dd/mm/yy).

(i) Replacement

If a part manufactured from non-conforming material is detected during the eddy current inspection required by paragraph (h) of this AD, within 30 days after doing the eddy current inspection, replace the affected part using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(j) Parts Installation Limitation

As of the effective date of this AD, an inboard flap may be installed on any airplane, provided the part is a serviceable part. A serviceable part is:

(1) A part that is not listed by serial number in figure 1 to paragraph (g) of this AD; or

(2) A part that has a serial number listed in figure 1 to paragraph (g) of this AD, but which has passed an eddy current conductivity measurement in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–57–3120, dated September 18, 2015; or Airbus Service

Bulletin A340–57–5036, dated September 18, 2015; as applicable.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1138; fax: 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0082, dated April 27, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8851.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com*; Internet: *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on August 18, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–20696 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 229

[Release No. 33–10198; 34–78687; File No. S7–18–16]

Request for Comment on Subpart 400 of Regulation S–K Disclosure Requirements Relating to Management, Certain Security Holders and Corporate Governance Matters

AGENCY: Securities and Exchange Commission.

ACTION: Request for comment.

SUMMARY: The Commission is requesting public comment on certain disclosure requirements in Regulation S–K relating to management, certain security holders, and corporate governance matters contained in Subpart 400. This request is part of an initiative by the Division of Corporation Finance to review the disclosure requirements in Regulation S–K to consider ways to improve them for the benefit of investors and registrants. Comments received in response to this request for comment will also inform the Commission's study on Regulation S–K, which is required by Section 72003 of the Fixing America's Surface Transportation Act ("FAST Act").

DATES: Comments should be received on or before October 31, 2016.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–18–16 in the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–18–16. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Web site (*http://www.sec.gov/rules/other.shtml*). Comments also are available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Eduardo A. Aleman, Special Counsel, Office of Rulemaking, Division of Corporation Finance, at (202) 551–3430, 100 F Street NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

Background and Discussion

Over the years, the Commission has evaluated its disclosure regime and engaged periodically in rulemakings designed to enhance its disclosure and registration requirements.[1] Most recently, the Commission published a concept release to seek public comment on modernizing certain business and financial disclosure requirements in Regulation S–K.[2] The purpose of the Regulation S–K Concept Release is to assess whether the business and financial disclosure requirements in Regulation S–K continue to provide the information that investors need to make informed investment and voting decisions. The Regulation S–K Concept Release focuses on the business and financial disclosures that registrants provide in their periodic reports, which are a subset of the disclosure requirements in Regulation S–K, because many of them have changed little since they were first adopted and are often the foundation of the disclosures investors look to when making investment decisions. These requirements have also been revisited by the Commission or the staff less frequently in the recent past than other disclosure requirements in Regulation S–K, such as executive compensation and governance contained in Subpart 400 of Regulation S–K.[3] Last year, the Commission also published a request for comment to seek public input about the financial disclosure requirements in Regulation S–X for certain entities other than a registrant.[4]

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[1] For a summary of the relevant history and background of Regulation S–K, *see Business and Financial Disclosure Required by Regulation S–K,* Release No. 33–10064 (Apr. 13, 2016) [81 FR 23916 (Apr. 22, 2016)] ("Regulation S–K Concept Release").

[2] *See id.*

These efforts, in addition to this request for comment, are part of a comprehensive evaluation of the Commission's disclosure requirements recommended in the staff's Report on Review of Disclosure Requirements in Regulation S–K ("S–K Study"), which was mandated by Section 108 of the Jumpstart Our Business Startups Act ("JOBS Act").[5] As noted in the Regulation S–K Concept Release, based on the S–K Study's recommendation and at the request of the Chair, Commission staff initiated a comprehensive evaluation of the type of information our rules require registrants to disclose, how this information is presented, where and how this information is disclosed, and how the Commission can leverage technology as part of these efforts (collectively, "Disclosure Effectiveness Initiative"). Section 72003(a) of the FAST Act[6] also requires the Commission to carry out a study of the requirements contained in Regulation S–K.[7] Specifically, Section 72003(a) requires that the study of Regulation S–K:

- Determine how best to modernize and simplify such requirements in a manner that reduces the costs and burdens on issuers while still providing all material information;
- Emphasize a company-by-company approach that allows relevant and material information to be disseminated to investors without boilerplate language or static requirements while preserving completeness and comparability of information across registrants; and
- Evaluate methods of information delivery and presentation and explore methods for discouraging repetition and the disclosure of immaterial information.[8]

Request for Comment

The initiative to review the disclosure requirements in Regulation S–K is intended to result in recommendations and proposals that will improve our disclosure system for the benefit of investors and registrants. The purpose of this request for comment is to solicit public input on Subpart 400 of Regulation S–K, which requires certain disclosures about a registrant's management, certain security holders, and corporate governance matters.[9] The input can include comments on existing requirements in these rules as well as on potential disclosure issues that commenters believe the rules should address.[10] The comments received in response to this request for comment, as well as comments received in response to the Regulation S–K Concept Release, will inform the Commission in carrying out the study of Regulation S–K required by Section 72003(a) of the FAST Act.[11]

- Item 401 of Regulation S–K generally requires certain disclosures about a registrant's directors, executive officers, promoters and control persons.[12]
- Item 402 of Regulation S–K generally requires disclosure of all plan and non-plan compensation awarded to, earned by, or paid to a registrant's named executive officers and directors.[13]
- Item 403 of Regulation S–K generally requires a description of the security ownership of certain beneficial owners and management.[14]
- Item 404 of Regulation S–K generally requires a description of certain transactions with related persons, promoters and certain control persons.[15]
- Item 405 of Regulation S–K generally requires a registrant to identify certain persons who failed to file on a timely basis, as disclosed in certain forms, reports required by Section 16(a) of the Securities Exchange Act[16] during the most recent fiscal year or prior fiscal years.[17]
- Item 406 of Regulation S–K generally requires disclosures about whether the registrant has adopted a code of ethics that applies to certain of the registrant's executive officers, or persons performing similar functions, and, if it has not adopted such a code of ethics, an explanation why it has not done so.[18]
- Item 407 of Regulation S–K generally requires certain corporate governance disclosure about director independence, board meetings, various board committees (*e.g.*, nominating, audit and compensation committees) and any process for shareholder communications.[19]

In connection with the staff's continuing Disclosure Effectiveness Initiative and corresponding work on the FAST Act mandate, the Commission welcomes public comments on the issues that the staff should consider in conducting its review of Subpart 400 of Regulation S–K, including, among other things, how best to modernize and simplify these disclosure items in view of the objectives of the Regulation S–K study set forth in Section 72003 of the FAST Act and whether additional disclosures in these areas are necessary or appropriate to facilitate investor protection, to maintain fair, orderly, and efficient markets, and/or to facilitate capital formation. In addition to the substance of the disclosure requirements, the Commission welcomes comments on how information can be presented to improve its readability, navigability and comparability and how technology and structured data can facilitate data aggregation and analysis. All interested parties are invited to submit their views and any data, in writing, on any matter relating to Subpart 400 of Regulation S–K.

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[3] *See, e.g., Executive Compensation and Related Person Disclosure,* Release No. 33–8732A (Aug. 29, 2006) [71 FR 53157 (Sept. 8, 2006)]; *Proxy Disclosure Enhancements,* Release No. 33–9089 (Dec. 16, 2009) [74 FR 68333 (Dec. 23, 2009)]; *Staff Observations in the Review of Executive Compensation Disclosure,* Division of Corporation Finance (Oct. 9, 2007), *available at https://www.sec.gov/divisions/corpfin/guidance/execcompdisclosure.htm.* As the Commission noted in the Regulation S–K Concept Release, the scope of that release does not include certain disclosure requirements for information other than business and financial disclosures, such as Subpart 400, which requires disclosure about management and certain security holders as well as corporate governance matters. *See* Regulation S–K Concept Release, *supra* note 1, at Section I, n. 4. This request for comment directly covers those subjects.

[4] *See Request for Comment on the Effectiveness of Financial Disclosures about Entities Other Than the Registrant,* Release No. 33–9929 (Sept. 25, 2015) [80 FR 59083 (Oct. 1, 2015)].

[5] Public Law 112–106, Sec. 108, 126 Stat. 306 (2012). Section 108 of the JOBS Act requires the Commission to conduct a review of Regulation S–K to determine how such requirements can be updated to modernize and simplify the registration process for emerging growth companies. The S–K Study is available at *http://www.sec.gov/news/studies/2013/reg-sk-disclosure-requirements-review.pdf.* For a further discussion of the S–K Study, see the *Regulation S–K Concept Release, supra* note 1, at Section II.C.

[6] Public Law 114–94, Sec. 72003, 129 Stat. 1312 (2015).

[7] In conducting this study, the Commission is required to consult with the Investor Advisory Committee and the Advisory Committee on Small and Emerging Companies.

[8] Public Law 114–94, Sec. 72003, 129 Stat. 1312 (2015).

[9] 17 CFR 229.401 *et seq.*

[10] For example, as noted in the *Regulation S–K Concept Release, supra* note 1, this could include industry-specific disclosure requirements, information about sustainability and governance matters, and additional instances in which scaled disclosure could be implemented.

[11] Comment letters received in response to this request for comment will be considered in connection with any future rulemaking related to the disclosure requirements in Subpart 400 of Regulation S–K. If the Commission proposes changes to these disclosure requirements the proposed changes will be subject to public notice and comment.

[12] 17 CFR 229.401.

[13] 17 CFR 229.402. Item 402 also describes the disclosure requirements for certain categories of registrants such as foreign private issuers and smaller reporting companies. The Commission has a number of outstanding proposals related to executive compensation disclosure and listing requirements. *See Disclosure of Hedging by Employees, Officers and Directors,* Release No. 33–9723 (Feb. 9, 2015) [80 FR 8485 (Feb. 17, 2015)]; *Pay Versus Performance,* Release 34–74835 (Apr. 29, 2015) [80 FR 26329 (May 7, 2015)]; *Listing Standards for Recovery of Erroneously Awarded Compensation,* Release No. 33–9861 (July 1, 2015) [80 FR 41143 (July 14, 2015)]. This release requests comment on the disclosure requirements in Item 402 generally and is not intended to solicit specific comment on those proposals.

[14] 17 CFR 229.403.

[15] 17 CFR 229.404.

[16] 15 U.S.C. 78p.

[17] 17 CFR 229.405.

[18] 17 CFR 229.406.

[19] 17 CFR 229.407.

By the Commission.

Dated: August 25, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–20906 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–442]

Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to temporarily schedule the opioids mitragynine and 7-hydroxymitragynine, which are the main active constituents of the plant kratom, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these opioids into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls applicable to schedule I controlled substances under the Controlled Substances Act on the manufacture, distribution, possession, importation, and exportation of, and research and conduct of instructional activities of these opioids.

DATES: August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Any final order will be published in the **Federal Register** and may not be effective prior to September 30, 2016.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.[1] The Administrator transmitted notice of his intent to place mitragynine and 7-hydroxymitragynine in schedule I on a temporary basis to the Assistant Secretary by letter dated May 6, 2016. The Assistant Secretary responded to this notice by letter dated May 18, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for mitragynine and 7-hydroxymitragynine. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of mitragynine and 7-hydroxymitragynine into schedule I of the CSA. Neither mitragynine nor 7-hydroxymitragynine is currently listed in any schedule under the CSA, and no approved new drug applications or investigational new drug applications for mitragynine or 7-hydroxymitragynine exist, 21 U.S.C. 355. The DEA has found that the control of mitragynine and 7-hydroxymitragynine in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C.

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[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Services (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Mitragynine and 7-hydroxymitragynine, the Main Active Constituents of the Plant Kratom

Mitragynine and 7-hydroxymitragynine are the main active constituents of the plant *Mitragyna speciosa* Korth (commonly known as kratom), an indigenous plant of Southeast Asia. Kratom is the only known species of Mitragyna to contain mitragynine and 7-hydroxymitragynine. Kratom is abused for its ability to produce opioid-like effects. Kratom is available in several different forms to include dried/crushed leaves, powder, capsules, tablets, liquids, and gum/resin. Consequently, kratom, which contains the main active constituents mitragynine and 7-hydroxymitragynine, is an increasingly popular drug of abuse and readily available on the recreational drug market in the United States. Attempted importations of kratom are routinely misdeclared and falsely labeled. This is similar to other attempts to import controlled substances or substances intended to mimic controlled substances. The amount of kratom material seized by law enforcement for the first half of 2016 greatly exceeds any previous year totals and easily accounts for millions of dosage units intended for the recreational market.[2] Available data and information for mitragynine and 7-hydroxymitragynine, the main active constituents of the plant kratom, and the plant kratom, are summarized below. Available information indicates that these opioid substances, constituents of the plant kratom, have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis is available in its entirety under of the public docket of this action as a supporting document at *www.regulations.gov* under Docket Number DEA–442.

Factor 4. History and Current Pattern of Abuse

Kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, has a long history of use in Southeast Asia as an opium substitute. Kratom is also known in Southeast Asia as thang, thom, krathom, kakuam, ketum, and biak. In recent years, the presence of the psychoactive plant kratom has increased dramatically on the recreational market in the United States due to its opioid-like effects. Numerous vendors selling kratom have appeared in the past few years, markedly increasing its availability.

Kratom preparations, which contain the main active alkaloids mitragynine and 7-hydroxymitragynine, are easily obtained from smoke shops and over the Internet. The Internet is the most utilized source for the purchase of kratom products, making kratom just "a click" away for users. In the United States, law enforcement has seized kratom/mitragynine products in the following forms: powder/plant, powder, plant or vegetable material, capsules, tablets, liquids, gum/resin, and drug patch.

Since abusers obtain kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragyine, through unknown sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to users. Several studies have analyzed the concentrations of mitragynine[3] and/or 7-hydroxymitragynine[4] in different kratom products. The studies showed that there were inconsistencies in the levels of the opioid mitragynine present in similar kratom products, and some products contained other psychoactive substances (see 3-factor analysis). Based on the variability of the mitragynine concentration in each product, users may experience differing effects when consuming similar amounts of different products.

Evidence suggests that kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, is abused individually, and with other psychoactive substances. In a 2016 publication, the Centers for Disease Control (CDC) characterized kratom exposures reported to poison centers and uploaded to the National Poison Data System (NPDS)[5] from January 2010 through December 2015. During the stated timeframe, U.S. poison centers received 660 calls related to kratom exposure. Of the calls reported, 487 (73.8%) reported intentional exposure to kratom, and 595 (90.2%) reported ingestion of the drug. In addition to reports of isolated exposures to kratom (428 (64.8%)), reports of kratom being used with other substances (ethanol, benzodiazepines, narcotics, acetaminophen, and other botanicals) were also recorded. Additionally, forensic laboratory analyses of drug evidence have identified kratom/mitragynine, along with synthetic cannabinoids and synthetic opioids during the analyses of products seized on the illicit market. The consumption of kratom individually, or in conjunction with alcohol or other drugs, is of serious concern as it can lead to severe adverse effects and death.

Kratom does not have an approved medical use in the United States and has not been studied as a treatment agent in the United States. Kratom has a history of being used as an opium substitute in Southeast Asia. Kratom has also been used to self-treat chronic pain and withdrawal symptoms from opioid use. Especially concerning, reports note users have turned to kratom as a replacement for other opioids, such as heroin.

In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms, with users reporting its effects to be comparable to prescription opioids. Users have also reported dose-dependent psychoactive effects to include euphoria, simultaneous stimulation and relaxation, analgesia, vivid dreams, and sedation (at higher doses). As noted in the actions by the United States Food and Drug Administration,[6] kratom products have been encountered with false claims, an extremely concerning issue for public health and safety. These products are marketed as safe for self-medication, but have not been approved by the Food and Drug Administration (FDA) for any medical uses.

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[2] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016.

[3] Mitragynine is the most abundant alkaloid in kratom and constitutes about 66 percent of the total alkaloid content of the plant. The alkaloid content of mitragynine was 45 percent of all alkaloids detected during analyses performed. Such large relative differences in proportions of plant alkaloids (66%:45%) are common among plant species and will lead to variations in potency and the risk of overdose.

[4] 7-Hydroxymitragynine is a more potent agonist than mitragynine although it only comprises about 1.6 percent of the total alkaloid content of the plant. The alkaloid content of 7-hydroxymitragynine was 4 percent of all alkaloids detected in analyses performed. Such large relative differences in proportions of plant alkaloids (4.0%:1.6%) are common among plant species and will lead to variations in potency and the risk of overdose.

[5] The National Poison Data System (NPDS) is a national database of information logged by the country's regional poison centers serving all 50 United States, Puerto Rico and the District of Columbia. The NPDS is maintained by the American Association of Poison Control Centers. NPDS case records are the result of call reports made by users (*i.e.*, self-reports), friends and family members, and health care providers.

Information from the published literature, poison control centers data, and medical examiner data, suggests that kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, is abused by a diverse population to include recreational opioid users, young adults, and adults. The most commonly described route of administration of kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, is oral. The leaves are typically brewed and ingested as a tea; however, smoking, chewing the raw leaves (done traditionally), and ingestion of kratom capsules or resin extracts have also been reported.

Factor 5. Scope, Duration and Significance of Abuse

The abuse of kratom, containing the main active alkaloids mitragynine and 7-hydroxymitragynine, is increasing in the United States and remains extremely concerning for law enforcement and public health. As the abuse of the plant increases, as demonstrated by the increasing availability per border encounters,[7] it has been noted that physicians should be aware of the kratom's adverse health effects, toxicity, dependence, and withdrawal .is.

Reports from law enforcement indicate that kratom is being imported for widespread distribution to the public within the United States.[8] Between February 2014 and July 2016, over 55,000 kilograms (kg) of kratom material were encountered by law enforcement at various ports of entry within the United States.[9] Additionally, over 57,000 kg of kratom material offered for import at numerous ports of entry, between 2014 and 2016, are awaiting an FDA admissibility decision.[10] The amount of kratom currently seized or awaiting an admissibility decision by law enforcement, between 2014 and 2016, is enough to produce over 12 million doses of kratom.[11] Such alarming quantities create an imminent public health and safety threat.

According to press announcements released in 2014 and 2016, the FDA requested the seizure, by US Marshals, of more than 25,000 pounds of raw kratom material, nearly 90,000 bottles of dietary supplements labeled as containing kratom, and over 100 cases of products labeled as kratom, respectively.[12] The FDA stated that kratom products "pose a risk to the public health and have the potential for abuse" and the seizure of certain kratom products was necessary "to safeguard the public from a dangerous product".[13] The FDA has also warned the public not to use any products labeled as containing kratom due to serious concerns about toxicity and potential health impacts.[14] To further protect the public health and safety from the large influx of kratom materials, the FDA issued and updated two import alerts related to numerous kratom and kratom-containing products.[15] These import alerts allow for detention without physical examination of dietary supplements and bulk ingredients that are or contain kratom, and detention without physical examination of unapproved new drugs promoted in the United States, which includes kratom products that make false health claims. Since 2014, 121 firms have been added to these import alerts for importing kratom products.[16]

Drug reports pertaining to the trafficking, distribution, and abuse of kratom/mitragynine [17] were analyzed by Federal, State, and local forensic laboratories.[18] According to data from the System to Retrieve Information from Drug Evidence (STRIDE) and STARLiMS (a web-based, commercial laboratory information management system), from January 2006 through March 2016, there were 293 records for kratom and/or mitragynine. From January 2010 through May 2016, the National Forensic Laboratory Information System (NFLIS) registered 720 reports containing mitragynine (See 3-Factor analysis). NFLIS and STRIDE/STARLiMS records/reports were reported across 43 States, thus showing the widespread abuse and trafficking of kratom/mitragynine.[19] The presence of these substances during drug evidence analyses demonstrates the presence of these substances on the recreational drug market.

Growing concern over the use of kratom is reflected in the increased requests for analyses of mitragynine and 7-hydroxymitragynine in human toxicology panels (blood/urine samples) [20] to private analytical laboratories.[21] These analyses have been requested by addiction treatment facilities/pain management doctors, drug courts, medical examiner/coroner offices, drug testing facilities, state laboratory systems, state police department, and private entities.[22] The number of positive results from these analyses increased as follows: 31 positive results from August 2012 to July 2013 for mitragynine and/or 7-hydroxymitragynine; [23] 274 positive results for mitragynine between July 2013 and May 2014; [24] 555 positive results for mitragynine between December 2014 and March 2016.[25] The increasing trend in the number of positive results from these analyses demonstrates the growing abuse and popularity of these substances and the concern related to the abuse of this plant material and its psychoactive constituents.

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[6] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016.

[7] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016.

[8] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016. Represents Customs and Border Patrol (CBP) seizures from February 2014 through July 2016.

[9] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016. Represents Customs and Border Patrol (CBP) seizures from February 2014 through July 2016.

[10] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016.

[11] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016. Assuming a high dose of 9 g of kratom.

[12] Relevant press release can be found online at: *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm416318.htm; http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm480344.htm;* and *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm515085.htm.*

[13] Relevant press release can be found online at: *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm416318.htm.*

[14] Relevant press release can be found online at: *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm515085.htm.*

[15] Relevant Import alerts (#'s 54–15 and 66–41) can be found online at: *www.accessdata.fda.gov/cms_ia/importalert_1137.html.and www.accessdata.fda.gov/cms_ia/importalert_190.html.*

[16] 2015–CDER–DEA Memorandum of Understanding for sharing information (Provided under 21 CFR 20.85) dated August 4, 2016.

[17] Mitrgynine is used to confirmatively identify plant material as kratom.

[18] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused.

[19] STRIDE, STARLiMS, and NFLIS data reflect data reported by the forensic laboratory systems. Encounters reported in these systems, and the overall number of seizures, may be low because kratom/mitragynine is not federally controlled under the CSA. Typically, after control, these numbers will increase.

[20] The quantitative values for mitragynine and 7-hydroxymitragynine were not available for all positive results shown.

[21] Substances are tested as part of a toxicology panel that includes illicit or commonly abused substances routinely analyzed.

[22] Email correspondences with analytical laboratories in Willow Grove, PA, Clearwater, FL, and Santa Rosa, CA.

[23] Located in Willow Grove, PA, analyzed blood/urine samples from Canada and thirteen U.S. states. Correspondences on file with DEA.

[24] Located in Clearwater, FL, analyzed urine samples from multiple states across the U.S. Correspondences on file with DEA.

Evidence from poison control centers in the United States also shows that there is an increase in the number of individuals abusing kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine. As such, there has been a steady increase in the reporting of kratom exposures by poison control centers. The American Association of Poison Control Centers identified two exposures to kratom between 2000 and 2005. Additionally, the Texas Poison Center Network (TPCN), which is comprised of six poison centers that service the State of Texas, reported 14 exposures to kratom between January 2009 and September 2013. Between January 2010 and December 2015 U.S. poison centers received 660 calls related to kratom exposure. During this time, there was a tenfold increase in the number of calls received, from 26 in 2010 to 263 in 2015.

Furthermore, the abuse and addictive properties of kratom, which contains the main active alkaloids mitragynine, and 7-hydroxymitragynine, have prompted at least 15 countries,[26] and 6 states and the District of Columbia to ban kratom, mitragynine and/or 7-hydroxymitragynine and two states within the United States,[27] to place regulatory controls on these substances. Six other States within the United States have proposed to ban or place regulatory controls on these substances.[28]

Internationally, the increased presence and abuse of kratom, containing the main active alkaloids mitragynine and 7-hydroxymitragynine, have garnered the attention of the International Narcotics Control Board (INCB).[29] In a 2010 report, the INCB noted the increased interest in the recreational use of kratom. The INCB recommended that governments experiencing problems with persons trafficking or using kratom [30] recreationally should consider controlling kratom and kratom preparations at the national level, where necessary.

Factor 6. What, if Any, Risk There Is to the Public Health

The use of kratom and associated products, which contains the main active alkaloids mitragynine and 7-hydroxymitragine, pose an imminent hazard to public safety. These substances produce opioid-like effects, making their abuse a serious public health concern. Information from published literature, public health officials, and poison control center data demonstrate that the use of kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragynine, has caused numerous adverse effects on users.

In a 2016 publication, the CDC characterized kratom exposures reported to poison centers and uploaded to the NPDS from January 2010 through December 2015.[31] These exposures resulted in medical outcomes that varied in severity, ranging from minor (having minimal signs or symptoms that resolved rapidly with no residual disability), moderate (having non-life threatening and no residual disability, but requiring some form of treatment), major (having life-threatening signs or symptoms with some residual disability), and death. Additionally, several adverse effects related to kratom exposure were reported, which include agitation or irritability, tachycardia, nausea, drowsiness, and hypertension. The severity of the reported outcomes, health effects, and increased use of kratom suggests an emerging public health threat.

Information from the scientific literature also demonstrates the health risks associated with kratom use. Reports of hepatotoxicity, psychosis, seizure, weight loss, insomnia, tachycardia, vomiting, poor concentration, hallucinations, and death associated with kratom use have been documented. Additionally, published case reports describe events where individuals sought medical care for the purported use of kratom. Some examples of the reported adverse events involving kratom exposure are described in the 3-factor analysis.

Numerous deaths associated with kratom, which contains the main active constituents mitragynine and 7-hydroxymitragynine, have been reported indicating that this substance is a serious public health threat. In 2016, DEA has received correspondences from public/state officials which indicate that there were a significant number of overdoses and traffic fatalities directly, or indirectly, involving kratom.[32] Deaths related to kratom exposure have been reported in the scientific literature beginning in 2009–2010, with a cluster of nine deaths in Sweden from use of the kratom product "Krypton". Since then, five more deaths related to kratom exposure were reported in the scientific literature, and sixteen other deaths related to kratom exposure, have been confirmed by autopsy/medical examiner reports (mitragynine and/or 7-hydroxymitragynine were identified in biological samples).[33] Of these deaths, 15 occurred between 2014 and 2016. This information demonstrates the severe risks associated with kratom misuse and the increasing occurrence of fatal outcomes related to kratom exposure. Details of some of these events are summarized in the 3-factor analysis.

Since abusers obtain kratom, which contains the main active alkaloids mitragynine and 7-hydroxymitragyine, through unknown sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to users. According to the FDA, in a letter dated May 18, 2016, there are no approved new drug applications, or investigational new drug applications for mitragynine or 7-hydroxymitragynine. As such, kratom products have no accepted medical use within the United States. Despite FDA warnings, kratom products continue to be easily available and abused by diverse populations. Distributors of kratom are knowingly putting the public at risk. Unknown factors including detailed product analysis and dosage variations between various packages present a significant danger to an abusing individual. With no accepted medical use, the abuse of kratom, which contains mitragynine and 7-hydroxymitragynine, poses an imminent hazard to the public safety.

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[25] Located in Santa Rosa, CA, analyzed urine samples from multiple states across the United States. Correspondences on file with DEA.

[26] Z. Aziz, *Kratom The Epidemiology, Use and Abuse, Addiction Potential, and Legal Status,* in Kratom and Other Mitragynines The Chemistry and Pharmacology of Opioids from a Non-Opium Source 309–319 (Raffa, R.B., ed 2014); European Monitoring Center for Drugs and Drug Addiction, Drug Profiles: Kratom, www.emcdda.europa.eu/publications/drug-profiles/kratom (accessed 08/28/2013); Misuse of Drugs Act 1977 Order 2011 (S.I. No. 551/2011) (Ir.); Misuse of Drugs (Amendment Regulations 2011 (S.I. No. 552/2011) (Ir.).

[27] Alabama—Ala. Code § 20–2–23; Arkansas—Ark. Admin. Code 007.07.2; Illinois—IL ST CH 720 § 642/5; Indiana—IC 35–31.5–2–321; Louisiana—LA R.S. 40:989.3; Tennessee—T.C.A. § 39–17–452; Vermont—Vt. Admin. Code 12–5–23:4.0; Wisconsin—W.S.A. 961.14 and District of Columbia—22–B DC ADC § 1201.

[28] New Hampshire—2015 NH S.B. 540 and 2015 NH S.B. 540; New Jersey—2016 NJ A.B. 3281; New York—2015 NY A.B. 9121, 2015 NY A.B. 9068, 2015 NY A.B. 8670, and 2015 NY S.B. 6345; North Carolina—2015 NC H.B. 747 (NS) and 2015 NC S.B. 830 (NS); Florida—2016 FL S.B. 1182 and 2016 FL H.B. 73; and Kentucky—2016 KY S.B. 136.

[29] The INCB is an independent monitoring body that is responsible for evaluating the implementation of the United Nations international drug controls conventions.

[30] Kratom was listed as a plant material containing psychoactive substances in the INCB report for which recommendations were made for specified plant materials.

[31] Calls from healthcare providers comprised a large portion of calls received, representing 75.2% of calls reported.

[32] Correspondences on file with DEA (dated April 19, 2016).

[33] Autopsy/Medical Examiner (ME) reports on file with DEA.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of mitragynine and 7-hydroxymitragynine pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for mitragynine and 7-hydroxymitragynine indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated May 6, 2016, notified the Assistant Secretary of the Department of Health and Human Services of the DEA's intention to temporarily place these substances in schedule I.

Conclusion

This notice of intent initiates an expedited temporary scheduling action and provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h). In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule mitragynine and 7-hydroxymitragynine in schedule I of the CSA, and finds that placement of these opioid substances into schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds that it is necessary to temporarily place these opioids into schedule I to avoid an imminent hazard to the public safety, any subsequent final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular scheduling process. 21 U.S.C. 811(h) (1) and (2). It is the intention of the Administrator to issue such a final order as soon as possible after the expiration of 30 days from the date of publication of this notice. Mitragynine and 7-hydroxymitragynine will then be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator will take into consideration any comments submitted by the Assistant Secretary with regard to the proposed temporary scheduling order.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(28) and (29) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(28) Mitragynine (to include synthetic equivalents as well as mitragynine naturally contained in the plant of the genus and species name: *Mitragyna speciosa* Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers . . . (9823)

(29) 7-Hydroxymitragynine (to include synthetic equivalents as well as 7-hydroxymitragynine naturally contained in the plant of the genus and species name: *Mitragyna speciosa* Korth, also known as kratom) its isomers, esters, ethers, salts and salts of isomers, esters and ethers . . . (9838)

Dated: August 25, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–20803 Filed 8–30–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2012–HA–0146]

RIN 0720–AB47

TRICARE; Reimbursement of Long Term Care Hospitals and Inpatient Rehabilitation Facilities

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The Department of Defense, Defense Health Agency, is proposing to revise its reimbursement of Long Term Care Hospitals (LTCHs) and Inpatient Rehabilitation Facilities (IRFs). Proposed revisions are in accordance with the statutory provision at title 10, United States Code (U.S.C.), section 1079(i)(2) that requires TRICARE payment methods for institutional care be determined, to the extent practicable, in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare. Our regulation includes a definition for "Hospital, long-term (tuberculosis, chronic care, or rehabilitation)." This rule proposes to delete this definition and create separate definitions for "Long Term Care Hospital" and "Inpatient Rehabilitation Facility" in accordance with Centers for Medicare & Medicaid Services (CMS) classification criteria. Under TRICARE, LTCHs and IRFs (both freestanding rehabilitation hospitals and rehabilitation hospital units) are currently paid the lower of a negotiated rate (if they are a network provider) or billed charges (if they are a non-network provider). Although Medicare's reimbursement methods for LTCHs and IRFs are different, it is prudent to propose adopting both the Medicare LTCH and IRF Prospective Payment System (PPS) methods simultaneously to align with our statutory requirement to utilize the same reimbursement system as Medicare. This proposed rule sets forth the proposed regulation modifications necessary for TRICARE to adopt Medicare's LTCH and IRF Prospective Payment Systems and rates applicable for inpatient services provided by LTCHs and IRFs to TRICARE beneficiaries.

DATES: Written comments received at the address indicated below by October 31, 2016 will be accepted.

ADDRESSES: You may submit comments, identified by docket number or Regulatory Information Number (RIN) and title, by either of the following methods:

The Web site: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, ATTN: Box 24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Sharon Seelmeyer, Defense Health Agency (DHA), Medical Benefits and Reimbursement Section, telephone (303) 676–3690.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

1. Long Term Care Hospitals (LTCHs)

This rule publishes TRICARE's proposed modifications to our regulation that are necessary to adopt the Medicare LTCH Prospective Payment System and rates. This is in accordance with the statutory requirement that for TRICARE institutional services "payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare]." Medicare pays LTCHs using a LTCH Prospective Payment System (PPS) which classifies LTCH patients into distinct Diagnosis-Related Groups (DRGs). The patient classification system groupings are called Medicare Severity Long Term Care Diagnosis Related Groups (MS–LTC–DRGs), which are the same DRG groupings used under the Medicare acute hospital inpatient prospective payment system (IPPS), but that have been weighted to reflect the resources required to treat the medically complex patients treated at LTCHs.

On January 26, 2015, a TRICARE proposed rule was published in the **Federal Register** [79 FR 51127], proposing to adopt a TRICARE LTCH PPS similar to the CMS' reimbursement system for LTCHs, with the exception of not adopting Medicare's LTCH 25 percent rule. However, that proposed rule acknowledged that the Department of Health and Human Services intended to address implementation of Section 1206(a) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) in their FY 2016 rulemaking process. As a result, the TRICARE proposed rule included a statement that DoD would "defer action on this issue pending review of the final Medicare policy." This review has been completed and we have changed our approach regarding implementation of the TRICARE LTCH PPS. Consequently, we are withdrawing the proposed rule published in the **Federal Register** on January 26, 2015, and publishing this new proposed rule to inform the public of our intent to adopt the CMS LTCH PPS system with no modifications or exceptions. We have determined that it is practicable to adopt Medicare's LTCH

PPS reimbursement methodology in its entirety without deviations.

On August 22, 2014, the CMS final rule on updating the annual payment rates for the Medicare PPS for inpatient hospital services provided by LTCHs was published in the **Federal Register** [79 FR 49853]. As part of its final rule, CMS discussed the need for future policy changes that would be required to carry out the provisions under section 1206 of the Pathway for SGR Reform Act of 2013, to include section 1206(a), which provides for the establishment of an alternate "site-neutral" payment rate for Medicare LTCH patients that fail to meet certain statutorily defined criteria, such as having been discharged by an IPPS hospital immediately preceding the LTCH admission, having 3 or more days in an ICU during the immediately preceding IPPS stay or having received at least 96 hours of respiratory ventilation services. If the above statutorily defined criteria is not met, the LTCH will receive a "site-neutral" payment rate. As mentioned earlier, as a result of the unspecified potential changes that might be required to Medicare's LTCH reimbursement system, a statement was added to TRICARE's proposed rule that DoD would defer action on adopting Medicare's potential changes relating to "site-neutral" payments until DoD could review the final Medicare policy. Upon review of Medicare's final rule published on August 17, 2015, we learned that significant changes had been made to Medicare's previous LTCH reimbursement system, specifically the precise details about the creation of Medicare's "site-neutral" payments beginning in FY 2016. This proposed rule explains our new reimbursement approach for LTCHs based on CMS' changes.

TRICARE pays for most hospital care under the TRICARE DRG-based payment system, which is similar to Medicare's, but some hospitals are exempt from the TRICARE DRG-based payment system. LTCHs are currently exempt from the TRICARE DRG-based payment system and are paid by TRICARE at the lower of a negotiated rate (if they are a network provider) or billed charges (if they are a non-network provider). Paying billed charges is fiscally imprudent and inconsistent with TRICARE's governing statute. Paying LTCHs under Medicare's methods is prudent, because it reduces government costs without affecting beneficiary access to services or quality; it is practicable, because it can be implemented without major costs; and it is harmonious with the statute because the statute states that TRICARE shall determine its payments for institutional services to the extent practicable in accordance with Medicare's payment rates. Our legal authority for this portion of the proposed rule is 10 U.S.C. 1079(i)(2).

2. Inpatient Rehabilitation Facilities (IRFs)

This rule also publishes proposed TRICARE regulation modifications necessary to adopt the Medicare IRF Prospective Payment System (PPS) and rates. This is in accordance with the statutory requirement that for TRICARE institutional services "payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare]." Medicare pays IRFs using an IRF Prospective Payment System (PPS) which classifies IRF patients into one of 92 case-mix groups (CMGs).

Similarly to LTCHs, IRFs, (both freestanding rehabilitation hospital and rehabilitation hospital units) are currently exempt from the TRICARE DRG-based payment system and are paid by TRICARE at the lower of a negotiated rate (if they are a network provider) or billed charges (if they are a non-network provider). As discussed earlier, paying billed charges is fiscally imprudent and inconsistent with TRICARE's governing statute. Paying IRFs under a method similar to Medicare's is prudent, practicable, and harmonious with the statute. Our legal authority for this portion of the proposed rule is 10 U.S.C. 1079(i)(2).

B. Summary of the Major Provisions of the Proposed Rule

1. Adoption of Medicare's Prospective Payment System Methodology for LTCHs

TRICARE proposes to reimburse LTCHs for inpatient care using Medicare's LTCH PPS using Medicare's MS–LTC–DRGs. Under the proposed TRICARE LTCH PPS reimbursement methodology, payment for a TRICARE patient will be made at a predetermined, per-discharge amount for each MS–LTC–DRG. The TRICARE LTCH PPS reimbursement methodology would include payment for all inpatient operating and capital costs of furnishing covered services (including routine and ancillary services), but not certain pass-through costs (*e.g.,* bad debts, direct medical education, and blood clotting factors). When the Medicare day limit is exhausted for TRICARE beneficiaries who are also eligible for Medicare (*i.e.,* TRICARE For Life (TFL) beneficiaries), TRICARE will be the primary payer for medically necessary services and the beneficiary will be responsible for the appropriate TRICARE inpatient cost share. We anticipate the beneficiary's out-of-pocket costs will be limited by the statutory catastrophic cap of $1,000 per family, per fiscal year for active duty family members and reserve select beneficiaries and $3,000 cap per family, per fiscal year for all other beneficiaries.

2. Transition Period

The Pathway for SGR Reform Act of 2013 directed CMS to make significant changes to the payment system for LTCHs. The law directs CMS to establish two different types of LTCH PPS payment rates depending on whether or not the patient meets certain clinical criteria: (1) Standard LTCH PPS payment rates; and (2) lower site-neutral LTCH PPS payment rates that are generally based on the Medicare acute hospital IPPS rates. Site-neutral patients include LTCH patients who do not use prolonged mechanical ventilation during their LTCH stay or who did not spend three or more days in the intensive care unit (ICU) during their prior acute care hospital stay. The law transitions the payment reductions in FY16 and FY17 by requiring payment based on a 50/50 blend of the standard LTCH PPS rate and the site-neutral LTCH PPS rate for site-neutral patients. In FY17, when we anticipate implementing the TRICARE LTCH PPS payment changes, we propose that TRICARE adopt Medicare's FY17 LTCH PPS payment policies, which will include Medicare's payment of site-neutral cases with Medicare's 50/50 blended payment for site-neutral patients. Medicare has not yet set the payment for site neutral cases for FY 2018, however, we will follow that payment rate once it is determined. For example, if the blended payment rate ends by FY18, we would also follow Medicare and all TRICARE site-neutral LTCH patients would receive the site-neutral payment (without a blend with the standard LTCH PPS rate). If implementation of the TRICARE LTCH PPS is delayed beyond FY17, there will be no transition period for site-neutral patients. Rather, TRICARE will adopt the Medicare LTCH PPS methodology applicable at the time of TRICARE implementation.

3. Adoption of Medicare's Prospective Payment System Methodology for IRFs

TRICARE proposes to reimburse IRFs for inpatient care using Medicare's IRF PPS which pays a prospectively-set, fixed payment per discharge based on a patient's classification into one of 92 case-mix groups (CMGs). Each CMG has a national relative weight reflecting the expected relative costliness of treatment for patients in that category compared with that for the average Medicare inpatient rehabilitation patient. The relative weight for each CMG is multiplied by a standardized Medicare IRF base payment amount to calculate the case-mix adjusted prospective payment rate. The TRICARE IRF PPS payment rates would cover all inpatient operating and capital costs that IRFs are expected to incur in furnishing intensive rehabilitation services. When the Medicare day limit is exhausted for TRICARE beneficiaries who are also eligible for Medicare (*i.e.,* TFL beneficiaries), TRICARE will be the primary payer for medically necessary services and the beneficiary will be responsible for the appropriate TRICARE inpatient cost share. We anticipate the beneficiary's out-of-pocket costs will be limited by the statutory catastrophic cap of $1,000 per family, per fiscal year for active duty family members and reserve select beneficiaries and $3,000 cap per family, per fiscal year for all other beneficiaries.

4. Removal of Outdated Terms

This proposed rule removes outdated definitions in 32 CFR 199.2 for "Hospital, long-term (tuberculosis, chronic care, or rehabilitation)" and "Long-term hospital care" and adds a new definition for "Long-Term Care Hospital (LTCH)" as well as adding a new definition for "Inpatient Rehabilitation Facility (IRF)." The new definitions are based on CMS' LTCH and IRF classifications. Our review of the data shows that there were no facilities reimbursed under our existing LTCH or IRF reimbursement methodologies that will not meet the new proposed definitions. The TRICARE requirements for both LTCHs and IRFs to be authorized institutional providers have been added to 32 CFR 199.6.

C. Costs and Benefits

The economic impact of the proposed rule is anticipated to reduce DoD allowed amounts to LTCHs by approximately $77 million during implementation if that occurs as planned in FY17, when TRICARE site-neutral cases will be paid based on a transitional 50/50 blended payment and $87 million if implemented in FY18 when site-neutral payments are fully phased-in. If implementation is delayed beyond FY17, TRICARE will use the Medicare fully phased in site-neutral payments for site-neutral patients. This proposed rule is also anticipated to reduce DoD allowed amounts to IRFs by approximately $53 million in FY17.

II. Introduction and Background

A. Reimbursement

1. TRICARE LTCH PPS Reimbursement

Patients with clinically complex problems, such as multiple acute or chronic conditions, may need hospital care for an extended period of time. LTCHs represent a relatively small number of hospitals (approximately 424 under Medicare), which treat a critically ill population with complex needs and long lengths of stay. Per 32 Code of Federal Regulations (CFR) 199.14(a)(1)(ii)(D)(*4*), LTCHs are currently exempt from the TRICARE DRG-based payment system, just as they were exempt from Medicare's Inpatient Prospective Payment System (IPPS) when the CMS initially implemented its DRG-based payment system. Because there is no alternate TRICARE reimbursement mechanism in 32 CFR part 199 at this time, LTCH inpatient care provided to TRICARE beneficiaries is currently paid the lower of a negotiated rate if a network LTCH, which is usually substantially greater than what would be paid using the TRICARE DRG method, or billed charges if a non-network LTCH.

Medicare created a PPS for LTCHs effective with the cost reporting period beginning on or after October 1, 2002. The MS–LTC–DRG system under Medicare's LTCH PPS classifies patients into distinct diagnostic groups based on their clinical characteristics and expected resource needs. The patient classification groupings, which are the same groupings used under the inpatient acute care hospital groupings (*i.e.,* MS–DRGs) are weighted to reflect the resources required to treat the medically complex patients who are treated in LTCHs. By their nature, LTCHs treat patients with comorbidities requiring long-stay, hospital-level care.

TRICARE often adopts Medicare's reimbursement methods but delays implementation generally until any transition phase is complete for the Medicare program. CMS included a 5-year transition period when it adopted LTCH PPS for Medicare, under which LTCHs could elect to be paid a blended rate for a set period of time. This transition period ended in 2006. Following the transition phase, in 2008 Medicare adopted an LTCH-specific DRG system, which uses MS–LTC–DRGs, as the patient classification method for LTCHs. In FY16, Medicare will begin its adoption of a site-neutral payment system for LTCHs. Beginning in FY16 and continuing in FY17, CMS is phasing in a site-neutral payment methodology; during the transition period in FY16 and FY17, for site-neutral patients, 50 percent of the allowed amount will be calculated using the site-neutral payment methodology and 50 percent will be calculated using the current full LTCH PPS standard federal payment rate methodology. Beginning in FY18, all Medicare payments for site-neutral patients will be calculated using the site-neutral payment methodology. Given TRICARE's statutory requirement to adopt Medicare's reimbursement methods when practicable, TRICARE is proposing to adopt Medicare's LTCH PPS reimbursement method for our beneficiaries, including the Medicare site-neutral payment methodology. TRICARE will adopt the Medicare payment methodology that is in place at the time of TRICARE's implementation. For example, for an FY17 implementation, we will follow Medicare and use a 50/50 blend of the site-neutral method and the full LTCH PPS payments for site-neutral patients use a 50/50 blend. If implementation is delayed beyond FY17, TRICARE will use the Medicare site-neutral payments for site-neutral patients.

Under 10 U.S.C. 1079(i)(2), the amount to be paid to hospitals, skilled nursing facilities, and other institutional providers under TRICARE, "shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare]." Based on 1079(i)(2), TRICARE is proposing to adopt Medicare's LTCH PPS as the methodology to reimburse TRICARE authorized LTCHs. A change is needed to conform to the statute.

For TRICARE, we were able to identify complete claims information for 678 patients who were Active Duty Service Members (ADSMs), their dependents, or retirees and their dependents who were not eligible for the TRICARE For Life program (referred to as non-TFL), and 56 TFL LTCH admissions in FY14, for which TRICARE was the primary payer for patients with no other health insurance (referred to as non-Other Health Insurance (OHI)). We also identified 27 non-TFL and 3 TFL non-OHI LTCH admissions in FY14 with incomplete claims data, and excluded these claims from the analysis. TRICARE allowed charges for non-TFL beneficiaries were approximately $73 million in FY14. We found that the average TRICARE allowed amount for non-TFL beneficiaries was approximately $107,000 in FY14, which is significantly more than the estimated amount that Medicare would have paid for these discharges (the average Medicare LTCH PPS payment would have been approximately $42,000). Using the Medicare LTCH PPS system would have reduced TRICARE-allowed amounts by almost $45 million in FY14 for non-TFL beneficiaries.

For TFL beneficiaries for whom TRICARE was the primary payer, TRICARE paid approximately $19 million in allowed charges in FY14. In cases where TRICARE is the primary payer for LTCH care of TFL beneficiaries, such as when a Medicare beneficiary exhausts his/her day limits, TRICARE is paying billed charges. Reimbursing using methods similar to the Medicare LTCH PPS methodology would have reduced TRICARE allowed charges for TFL beneficiaries by approximately $15 million in FY14.

Shifting to methods similar to the Medicare LTCH PPS methodology would have reduced TRICARE allowed charges to LTCHs for non-TFL and TFL beneficiaries by $60 million in FY14 and is expected to reduce allowed charges by $77 million in FY17, assuming that site-neutral payments will be based on a 50/50 blend of the standard LTCH PPS rate and the site-neutral LTCH PPS rate. We projected savings in FY17 by first projecting costs under TRICARE's current policy for reimbursing LTCHs. We assumed that the costs would increase by 7 percent per year from FY14 to 17 reflecting increases in both TRICARE admissions to LTCHs under current policy and increases in TRICARE billed charges. We then projected the costs under the proposed policy assuming that under the Medicare LTCH–PPS the combination of admissions and higher reimbursement rates would increase costs by 3 percent per year. This percentage annual increase in TRICARE allowed amounts using the LTCH–PPS is less than the current policy percentage increase to reflect lower rates of increases in LTCH reimbursement rates under the LTCH–PPS (in comparison to TRICARE billed charges) and fewer LTCH admissions due to the phased in implementation of the Medicare LTCH site-neutral policy. The difference between the current policy and proposed policy amounts was equal to savings of $77 million in FY17, assuming partial phase-in of site-neutral payments.

As discussed above, TRICARE's current payment method results in TRICARE reimbursing LTCHs substantially more than Medicare does for equivalent inpatient care. Adopting Medicare's LTCH PPS methodology is practicable. Even though the beneficiary populations differ between Medicare and TRICARE non-TFL beneficiaries, we have found that the distribution of LTCH cases by diagnosis groups is similar between the two populations. To adjust for the differences in use by the TRICARE and Medicare populations, we considered developing TRICARE-specific weights and rates. However, TRICARE has a low volume of admissions to LTCHs, so calculating weights and rates for TRICARE admissions to LTCHs is impracticable. We are able to calculate our own weights for admissions to general hospitals on an annual basis because of the volume of TRICARE admissions to general hospitals; however, it would be difficult to determine a new set of TRICARE LTCH weights because of the small number of TRICARE admissions. For example, there were only about 700 TRICARE admissions in FY14 in the approximately 750 MS–LTC–DRG groups. Only four MS–LTC–DRGs had 25 or more TRICARE admissions in FY14 and only 14 had ten or more TRICARE admissions in that year. Approximately 600 MS–LTC–DRGs had no TRICARE LTCH admissions. Consequently, we are proposing to adopt the weights and rates used currently in Medicare's MS–LTC–DRGs.

Further, TRICARE proposes to adopt Medicare's LTCH PPS to include short-stay outliers, the 25 percent threshold payment adjustment, site-neutral payments, interrupted stay policy, the method of payment for preadmission services, and high-cost outlier payments. TRICARE also proposes to incorporate Medicare's Long Term Care Hospital Quality Reporting (LTCHQR) payment adjustments for TRICARE LTCHs that reflect Medicare's annual payment update for that facility. TRICARE is not establishing a separate reporting requirement for hospitals, but will utilize Medicare's payment adjustments resulting from their LTCHQR Program. Please see Medicare's final rule [CMS–1632–F; CMS–1632–CN2] RIN 0938–AS41.

2. TRICARE IRF PPS Reimbursement

IRFs are free standing rehabilitation hospitals and rehabilitation units in acute care hospitals that provide an intensive rehabilitation program. Per 32 CFR 199.14(a)(1)(ii)(D)(*2*) and (*3*), IRFs are currently exempt from the TRICARE DRG-based payment system, just as they were exempt from Medicare's IPPS when the CMS initially implemented its DRG-based payment system. Per 42 CFR 412.1(a)(1), an inpatient rehabilitation hospital or rehabilitation unit of an acute care hospital must meet the requirement for classification as an IRF stipulated in subpart B of 42 CFR part 412. One criterion specified at 42 CFR 412.29(b)(1) that Medicare uses for classifying a hospital or unit of a hospital as an IRF is that a minimum percentage (currently 60 percent) of a facility's total inpatient population must meet at least one of 13 medical conditions listed in 42 CFR 412.29(b)(2). Because there is no alternate TRICARE reimbursement mechanism in 32 CFR part 199 at this time, IRF care provided to TRICARE beneficiaries in this setting is currently paid the lower of a negotiated rate if a network IRF, or billed charges if a non-network IRF.

Medicare created a PPS for IRFs effective with the cost reporting period beginning in January 2002. Section 4421 of the Balanced Budget Act of 1997 (Pub. L. 105–33) modified how Medicare payment for IRF services is to be made by creating Section 1886(j) of the Social Security Act, which authorized the implementation of a per-discharge prospective payment system for inpatient rehabilitation hospitals and rehabilitation units of acute care hospitals—referred to as IRFs. As required by Section 1886(j) of the Act, the Federal rates reflect all costs of furnishing IRF services (routine, ancillary, and capital related). CMS included a 9-month transition period when it adopted the IRF PPS for Medicare, under which IRFs could elect to be paid a blended rate. The transition period ended October 1, 2002. Following the transition period, payment to all IRFs was based entirely on the prospective payment.

Under 10 U.S.C. 1079(i)(2), the amount to be paid to hospitals, skilled nursing facilities, and other institutional providers under TRICARE, "shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare]." Based on 1079(i)(2), TRICARE is proposing to adopt Medicare's reimbursement methodology to reimburse TRICARE authorized IRFs. A change is needed to conform to the statute.

For TRICARE, we were able to identify complete claims information for 2,929 TRICARE beneficiaries discharged from IRFs in FY14 where TRICARE was the primary payer. TRICARE allowed charges for these beneficiaries was approximately $121 million in FY14. These allowed amounts were equal to 74 percent of billed charges, indicating that there were significant discounts offered by IRFs. Excluding Children's and Veterans (VA) hospital claims, which are not paid under the IRF–PPS, TRICARE allowed amounts were $89 million in FY14. We found that the average allowed amount per IRF stay (excluding Children's and VA hospital claims) was $34,300 in FY14, which is significantly more than the estimated amount that Medicare would have paid for these discharges (the average Medicare IRF PPS payment was approximately $18,600 in 2014). The 2014 Medicare payment amount per case was reported in the 2016 Medicare Payment Advisory Commission (MedPAC) report. Using the Medicare IRF PPS system would have reduced TRICARE allowed amounts by approximately $41 million in FY14.

Given TRICARE's statutory requirement to adopt Medicare's reimbursement methods when practicable, TRICARE is proposing to adopt Medicare's IRF PPS reimbursement method for its beneficiaries who receive rehabilitative care in IRFs. TRICARE proposes to adopt Medicare's IRF PPS and include Medicare's adjustments for interrupted stays, short stays of less than three days, short-stays transfers (defined as transfers to another institutional setting with an IRF length of stay less than the average length for the CMG), and high-cost outliers. TRICARE proposes to not adopt Medicare's low-income payment (LIP) adjustment for IRFs, because TRICARE does not adjust for Disproportionate Share in acute care hospitals under the TRICARE DRG system. TRICARE also proposes to incorporate Medicare's Inpatient Rehabilitation Hospital Quality Reporting (IRFQR) payment adjustments for TRICARE IRFs, that reflect Medicare's annual payment update for that facility. TRICARE is not establishing a separate reporting requirement for hospitals, but will utilize Medicare's payment adjustments resulting from their IRFQR Program. Please see Medicare's final rule [CMS–1632–F; CMS–1632–CN2] RIN 0938–AS41.

B. Pediatric Cases

1. LTCH

Our analysis found that the TRICARE pediatric LTCH patients and Medicare populations have similar diagnoses and that the estimated TRICARE costs in each MS–LTC–DRG group are similar to those in Medicare. There are very few TRICARE LTCH cases for patients under age 17; however, these pediatric cases have similar diagnoses as other TRICARE LTCH admissions. Therefore, we propose to adopt the same LTCH PPS methodology for pediatric patients in LTCHs as we are for all other TRICARE beneficiaries.

We are inviting comments on this proposal and welcome feedback on whether the MS–LTC–DRG weights are appropriate for pediatric cases. We also welcome options and alternative approaches for consideration in establishing LTCH reimbursement for pediatric beneficiaries.

2. IRF

In 2014, approximately 50 patients under the age of 17 received IRF care under TRICARE. Approximately 38 percent of those TRICARE pediatric IRF cases were treated at Children's hospitals, which are exempt from Medicare's IRF PPS. TRICARE is proposing that pediatric rehabilitation cases at Children's hospitals would also be exempt under the TRICARE IRF PPS and instead paid under the TRICARE DRG system. Pediatric cases treated at TRICARE IRFs would be paid under the TRICARE IRF PPS.

C. Veterans (VA) Hospitals

VA hospitals specialize in treating injured veterans and provide access to rehabilitative care. VA hospitals are not Medicare authorized IRFs (because they are Federal hospitals) and they do not use Medicare's IRF PPS method. TRICARE allows VA hospitals to provide inpatient rehabilitation care to TRICARE beneficiaries, and VA hospitals provide care for over 200 TRICARE patients each year (mostly Active Duty Service Members (ADSMs)). VA hospitals will continue to be paid under existing methodologies.

III. Regulatory Impact Analyses for LTCHs and IRFs

A. Overall Impact

DoD has examined the impacts of this proposed rule as required by Executive Orders (E.O.s) 12866 (September 1993, Regulatory Planning and Review) and 13563 (January 18, 2011, Improving Regulation and Regulatory Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

1. Executive Order 12866 and Executive Order 13563

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

We estimate that the effects of the LTCH and IRF provisions that would be implemented by this rule would not result in LTCH or IRF revenue reductions exceeding $100 million in any one year individually; however, when combined, revenue reductions would exceed $100 million, making this rulemaking "economically significant" as measured by the $100 million threshold. We have prepared Regulatory Impact Analyses that, to the best of our ability, presents the costs and benefits of the rulemaking. This proposed rule is anticipated to reduce DoD allowed amounts to LTCHs by $77 million and to IRFs by $53 million in FY17.

2. Congressional Review Act. 5 U.S.C. 801

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This Notice of Proposed Rule Making is a major rule under the Congressional Review Act.

3. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals are considered to be small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) identification of a small business (having revenues of $34.5 million or less in any one year). For purposes of the RFA, we have determined that the majority of LTCHs and all IRFs would be considered small entities according to the SBA size standards. Individuals and States are not included in the definition of a small entity. Therefore, this Rule would have a significant impact on a substantial number of small entities. The Regulatory Impact Analyses, as well as the contents contained in the preamble, also serves as the Regulatory Flexibility Analysis.

4. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $140 million. This Proposed Rule will not mandate any requirements for State, local, or tribal governments or the private sector.

5. Paperwork Reduction Act

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3502–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized. We do not anticipate any increased costs to hospitals because of paperwork, billing, or software requirements since we are keeping TRICARE's billing/coding requirements (*i.e.*, hospitals will be coding and filing claims in the same manner as they currently are with TRICARE).

6. Executive Order 13132, "Federalism"

This rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

B. Hospitals Included in and Excluded From the Proposed LTCH and IRF PPS Reimbursement Methodologies

The TRICARE LTCH PPS and the TRICARE IRF PPS encompass all Medicare-classified LTCHs and IRFs that are also authorized by TRICARE and that have inpatient stays for TRICARE beneficiaries, except for hospitals in States that are paid by Medicare and TRICARE under a waiver that exempts them from Medicare's inpatient prospective payment system or the CHAMPUS DRG-based payment system, respectively. Currently, only Maryland hospitals operate under such a waiver.

C. Analysis of the Impact of Policy Changes on Payment for LTCH and IRF Alternatives Considered

The alternatives that were considered, the changes that we are proposing, and the reasons that we have chosen these options are discussed below.

1. Alternatives Considered for Addressing Reduction in LTCH Payments

Under the method discussed here, TRICARE's LTCH payments per discharge would decrease by an average of 45–75 percent for most LTCHs. Because the impact of moving from a charge-based reimbursement method to Medicare's method would produce such large reductions in the TRICARE allowed amounts for LTCH care, we considered a 4-year phase-in of this approach. Under this option, one portion of the payment would continue to be paid as the billed charge and the remaining portion would be paid under the Medicare approach. In the first year, 75 percent of the payment would be based on billed charges and in each subsequent year this portion would be reduced by 25 percentage points so that by the fourth year the billed charge portion would be zero points.

For the following reasons, we have determined that a transition period is unnecessary because the Medicare-based payment amounts will have a minimal impact on overall LTCH payments and to any particular LTCH under TRICARE. First, the TRICARE payments to LTCHs will be equal to Medicare's LTCH payments. The Medicare Payment Advisory Committee (MedPAC) is an independent congressional agency which advises the U.S. Congress on issues affecting the Medicare program. MedPAC's most recent research indicates that Medicare LTCHs have a positive Medicare margin. Second, the number of TRICARE discharges from LTCHs is very small in comparison to the number of Medicare discharges in LTCHs each year. In FY14, there were 764 discharges to LTCHs in which TRICARE was the primary payer (including the 30 discharges with incomplete data). Medicare, in comparison, had approximately 138,000 discharges to LTCHs in 2013. Thus, in aggregate, the TRICARE LTCH claims are a very small percentage of the industry's claims (about one-half of one percent). Third, we found that in FY14 there were only 5 LTCHs with 15 or more TRICARE admissions. For all but two TRICARE LTCHs, we found that TRICARE admissions accounted for less than six percent of the number of Medicare discharges. Of the 212 LTCHs with TRICARE discharges, we found that 154 had 3 or fewer discharges in FY14 and that 208 Medicare LTCHs had no admissions in FY14 where TRICARE was the primary payer. Thus, the number of TRICARE discharges at any one LTCH is small and TRICARE is a small portion of LTCH revenues. Fourth, we do not think that there will be access problems for TRICARE beneficiaries. MedPAC has analyzed LTCH access for Medicare patients and concluded that Medicare beneficiaries have continued access to LTCHs under the Medicare payment methodology proposed here as evidenced by an increasing supply of providers and an increasing number of LTCH stays. Given that the TRICARE LTCH rates will equal Medicare LTCH rates and will have a limited impact on overall LTCH payments, we do not anticipate access problems for TRICARE beneficiaries. Further, by statute, hospitals that participate under Medicare are required to agree to accept TRICARE reimbursement. In summary, for these four reasons we do not think that a transition period is necessary, but we invite comments on this approach.

2. Alternatives Considered for Addressing Reduction in IRF Payments

Under the method discussed here, TRICARE's IRF payments per discharge would decrease by 30–40 percent for most IRFs. Because the impact of moving from a charge-based reimbursement method to Medicare's method would produce such large reductions in the TRICARE allowed amounts for IRF care, we considered a 3-year phase-in of this approach. Under this option, one portion of the payment would continue to be paid as the billed charge and the remaining portion would be paid under the Medicare approach. In the first year, two-thirds of the payment would be based on billed charges and in each subsequent year this portion would be reduced by one-third so that by the third year the billed charge portion would be zero points.

For the following reasons, we have determined that a transition period is unnecessary because the Medicare-based payment amounts will have a minimal impact on overall LTCH payments and to any particular LTCH under TRICARE. First, the TRICARE payments to IRFs will be equal to Medicare's IRF payments. The Medicare Payment Advisory Committee (MedPAC) is an independent congressional agency which advises the U.S. Congress on issues affecting the Medicare program. MedPAC's most recent research from March 2015 indicates that Medicare IRFs generally have positive Medicare margins. Thus, we think that IRFs will earn a positive margin from TRICARE. Second, the number of TRICARE discharges from IRFs is very small in comparison to the number of Medicare IRF discharges each year. In FY14, there were 2,681 IRF discharges in which TRICARE was the primary payer (including the 78 discharges with incomplete data and excluding discharges from Children's and VA hospitals). Medicare, in comparison, had approximately 376,000 IRF stays in 2014. Thus, in aggregate, the TRICARE IRF claims account for less than one percent of the industry's claims. Third, we found that in FY14 there were only 24 IRFs with 20 or more TRICARE admissions. For all but nine TRICARE IRFs, we found that TRICARE admissions accounted for less than ten percent of the number of Medicare discharges. Of the 591 IRFs with TRICARE discharges (including the 23 with incomplete data), we found that 408 had 3 or fewer discharges in FY14 and that 771 Medicare IRFs had no TRICARE admissions in FY14 where TRICARE was the primary payer. Thus, the number of TRICARE discharges at any one IRF is small and TRICARE accounts for a small portion of IRF revenues. Fourth, we do not think that there will be access problems for TRICARE beneficiaries. MedPAC has analyzed IRF access for Medicare patients and concluded that Medicare beneficiaries have continued access to IRFs. MedPAC reports the number of providers and volume of services in IRFs has remained stable between 2012 and 2013. Because the TRICARE IRF rates will equal Medicare IRF rates and will have a limited impact on overall LTCH payments, we do not anticipate access problems for TRICARE beneficiaries. Further, by statute, hospitals that participate under Medicare are required to agree to accept TRICARE reimbursement. In summary, for these four reasons we do not think that a transition period is necessary, but we invite comments on this approach.

D. Analysis of the Impact of TRICARE LTCH and IRF Payment Reform on LTCHs and IRFs

1. LTCH Methodology

We analyzed the impact of TRICARE implementing a new method of payment for LTCHs. The proposed method is Medicare's LTCH payment method, which uses the Medicare MS–LTC–DRG system for cases that meet specific clinical criteria to qualify for the standard LTCH PPS payment rates and, as of FY17, the Medicare IPPS MS–DRG system for all other (site-neutral) patients. Our analysis compares the impact on allowed charges of the new methodology compared to current TRICARE methodology (where TRICARE pays billed charges or discounts off of these billed charges for all LTCH claims).

The data used in developing the quantitative analyses presented below are taken from TRICARE allowed charge data from October 2013 to September 2014. We drew upon various sources for the data used to categorize hospitals in Table 1, below. We attempted to construct these variables using information from Medicare's FY14 Impact file to verify that each provider was in fact a Medicare LTCH. One limitation is that for individual hospitals, some miscategorizations are possible. We were unable to match 30 hospital claims from 6 LTCHs to the FY14 Impact file, and as a result, these claims were excluded from the analysis. All Maryland LTCHs were also excluded from the analysis. After we removed the excluded claims which we could not assign charge and hospital classification variables for, we used the remaining hospitals and claims as the basis for our analysis.

Using allowed charge data from 2014, the FY14 Medicare MS–LTC–DRG and MS–DRG weights, the FY14 Medicare LTCH and IPPS national base payment rates, the FY14 Medicare high cost outlier fixed thresholds, and the FY14 wage index adjustment factors, we simulated TRICARE allowed amounts in FY14 using the proposed LTCH prospective payment method. We focused the analysis on TRICARE claims where TRICARE was the primary payer because only these TRICARE payments will be affected by the proposed reforms.

2. IRF Methodology

We analyzed the impact of TRICARE implementing a new method of payment for IRFs. The proposed method is Medicare's IRF prospective payment system (PPS) method, which pays a prospectively-set fixed payment per discharge based on a patient's classification into one of 92 case-mix groups (CMGs). Our analysis compares the impact on allowed charges of the new methodology compared to current TRICARE methodology (where TRICARE pays billed charges or discounts off of these billed charges for all IRF claims).

The data used in developing the quantitative analyses presented below are taken from TRICARE allowed charge data from October 2013 to September 2014. We drew upon various sources for the data used to categorize hospitals in Table 1, below. We attempted to construct these variables using information from Medicare's FY16 IRF rate setting file and the Medicare Provider file to verify that each TRICARE IRF provider was in fact a Medicare IRF. One limitation is that for individual hospitals, some miscategorizations are possible. We were unable to match 78 IRF claims from 23 IRFs to Medicare provider numbers within the FY16 IRF rate setting file or the October 2015 Medicare IRF PSF file, and as a result, these claims were excluded from the analysis. We also excluded all Children's Hospital (4 hospitals, 22 discharges) and all Veterans hospital (12 Veterans hospitals, 226 discharges) claims because these hospitals are not paid under the Medicare IRF–PPS. After we removed the excluded claims which we could not assign charge and hospital classification variables for, we used the remaining hospitals and claims as the basis for our analysis.

The impact of adopting the Medicare IRF–PPS is difficult to estimate because there is insufficient diagnosis information on the TRICARE claims to classify TRICARE patients into a CMG. Because we were unable to classify TRICARE discharges into one of the 92 Medicare CMGs, we took an alternative approach to estimate the costs of adopting the Medicare IRF–PPS system. Our approach is based on first calculating the facility-specific "Medicare" costs for TRICARE IRF discharges at each IRF using the FY14 TRICARE billed charges at that IRF and the Medicare cost-to-charge ratio (CCR) for that IRF. We then used Medicare payment and cost data from the FY16 Medicare IRF rate setting file to calculate the Medicare margin at each IRF. In a third step of our approach we multiplied the estimated cost of each TRICARE discharge calculated in the first step by the IRF-specific margin to get an estimate of the allowed amount that would be paid by TRICARE under the Medicare IRF–PPS for each discharge. Under "current policy" we assumed that TRICARE IRF costs would increase by 6 percent per year from FY14 to FY17 to reflect increases in billed charges. We then projected the costs under the proposed policy, assuming that under the Medicare IRF–PPS, costs would increase by 2.5 percent per year from FY14 to FY17. Under the Medicare IRF–PPS, the percentage annual increase of 2.5 percent in TRICARE allowed amounts is less than the percentage increase under current policy due to slower increases in Medicare IRF reimbursement rates (in comparison to TRICARE billed charges). The difference between the current and the proposed policy was equal to $53 million in FY17. As a result, this approach allows us to estimate the change in allowed amounts under the Medicare method without having CMG data on TRICARE patients. We focused the analysis on TRICARE claims where TRICARE was the primary payer because only these TRICARE payments will be affected by the proposed reforms.

3. Effect on Hospitals

Table 1, Impact of TRICARE LTCH Rule in FY14, Assuming Full Implementation of the Medicare Site-Neutral Payment Policy, below, presents the results of our analysis of FY14 TRICARE claims data. This table categorizes LTCHs which had TRICARE inpatient stays in FY14 by various geographic and special payment consideration groups to illustrate the varying impacts on different types of LTCHs. The first column represents the number of LTCHs in FY14 in each category which had inpatient stays in which TRICARE was the primary payer. The second column shows the number of TRICARE discharges in each category. The third column shows the average TRICARE allowed amount per discharge in FY14. The fourth column shows the simulated average allowed amount per discharge under the Medicare LTCH payment method, assuming full implementation of the Medicare site-neutral payment policy. The fifth column shows the percentage reduction in the allowed amounts under the full implementation of the Medicare site-neutral method relative to the current allowed amounts.

The first row in Table 1 shows the overall impact on the 222 LTCHs included in the analysis. The next three rows of the table contain hospitals categorized according to their urban/rural status in FY14 (large urban, other urban, and rural). The second major grouping is by LTCH bed-size category, followed by TRICARE network status of the LTCH. The fourth grouping shows the LTCHs by regional divisions while the final grouping is by LTCH ownership status.

We estimate that in FY14, assuming full implementation of the Medicare site-neutral payment policy, TRICARE allowed amounts to LTCHs would have decreased by 67 percent in comparison to allowed amounts paid to LTCHs under the current TRICARE policy. For all groups of LTCHs, allowed amounts under the proposed payment methodology would have been reduced.

The following discussion highlights some of the changes in allowed amounts among LTCH classifications. Ninety-six percent of all TRICARE LTCH admissions were to urban LTCHs. Allowed amounts would have decreased by 69 percent for large urban, 64 percent for other urban, and 71 percent for rural LTCHs.

Very small LTCHs (1–24 beds) would have had the least impact; allowed amounts would have been reduced by 49 percent. The change in payment methodology would have had the greatest impact on large LTCHs (125 or more beds), where allowed amounts would have been reduced by about 72 percent.

The change in LTCH payment methodology would have a larger impact on TRICARE non-network LTCHs than network LTCHs because network LTCHs currently offer a discount off billed charges while non-network LTCHs do not. Allowed charges to non-network LTCHs would have declined by 74 percent, in comparison to 64 percent for in-network hospitals. We found that network hospitals on average provide a 30 percent discount off billed charges for non-TFL TRICARE beneficiaries and that 79 percent of all TRICARE LTCH discharges were in-network in FY14.

LTCHs in various geographic areas would have been affected differently due to this change in payment methodology. The two regions with the largest number of TRICARE claims, the South Atlantic and West South Central region, would have had an average decrease of 68 and 69 percent in allowed charges respectively, which are very similar to the overall average of 67 percent. LTCHs in the East North Central and West North Central regions would have had the lowest reductions in allowed charges: 59 and 45 percent, respectively.

Seventy-nine percent of all TRICARE LTCH discharges in FY14 were in proprietary (for-profit) LTCHs, and these facilities would have had their allowed amounts reduced by approximately 68 percent. The decline in allowed amounts for voluntary (not-for-profit) LTCHs would have been less than for-profit hospitals (63 percent).

TABLE 1—IMPACT OF TRICARE LTCH RULE IN FY14, ASSUMING FULL IMPLEMENTATION OF THE MEDICARE SITE-NEUTRAL PAYMENT POLICY

	Number of LTCHs with TRICARE stays	Number of TRICARE discharges	Allowed per discharge (current policy)	Allowed per discharge (Medicare method)	Percent reduction in allowed amounts
All LTCHs	222	734	$125,235	$41,071	67
Large Urban	110	405	148,099	46,255	69
Other Urban	103	312	96,193	34,787	64
Rural	9	17	113,576	32,880	71
Beds	222	734	125,235	41,071	67
1–24	7	13	53,921	27,635	49
25–34	42	103	107,786	38,029	65
35–49	55	164	114,849	39,252	66
50–74	63	205	108,308	36,920	66
75–124	35	151	137,763	44,779	67
125+	20	98	186,523	52,064	72
Network Status	222	734	125,235	41,071	67
Network	160	580	110,147	39,461	64
Non-Network	62	154	182,062	47,133	74
Region	222	734	125,235	41,071	67
New England	5	15	74,012	24,186	67
Mid Atlantic	11	22	121,182	29,631	76
South Atlantic	39	238	131,922	41,939	68
East North Central	32	71	93,975	38,786	59
East South Central	19	54	146,180	46,381	68
West North Central	13	27	87,161	48,098	45
West South Central	68	214	104,033	31,831	69

TABLE 1—IMPACT OF TRICARE LTCH RULE IN FY14, ASSUMING FULL IMPLEMENTATION OF THE MEDICARE SITE-NEUTRAL PAYMENT POLICY—Continued

	Number of LTCHs with TRICARE stays	Number of TRICARE discharges	Allowed per discharge (current policy)	Allowed per discharge (Medicare method)	Percent reduction in allowed amounts
Mountain	18	56	166,254	60,533	64
Pacific	17	37	223,154	64,625	71
Ownership	222	734	125,235	41,071	67
Proprietary	175	567	127,929	40,763	68
Government Owned	10	29	108,139	32,452	70
Voluntary	37	138	117,760	44,147	63

Source: FY14 TRICARE LTCH claims and FY14 Medicare Impact File. Excludes claims with other health insurance (OHI). Amounts adjusted for FY14 Wage Index and FY14 COLA.

Note: Excludes 30 claims from 6 TRICARE LTCHs that did not have a cost-to-charge ratio (CCR) in the FY14 Medicare Impact File.

Table 2, Impact of TRICARE IRF Rule in FY14, presents the results of our analysis of FY14 TRICARE claims data. This table categorizes IRFs which had TRICARE inpatient stays in FY14 by various geographic and special payment consideration groups to illustrate the varying impacts on different types of IRFs. The first column represents the number of IRFs in FY14 in each category which had inpatient stays in which TRICARE was the primary payer. The second column shows the simulated number of TRICARE discharges in each category. The third column shows the average TRICARE allowed amount per discharge in FY14. The fourth column shows the average allowed amount per discharge under the Medicare IRF payment method, excluding the LIP adjustment. The fifth column shows the percentage reduction in the allowed amounts under the Medicare payment method relative to the current TRICARE allowed amounts.

The first row in Table 2 shows the overall impact on the 568 IRFs included in the analysis. The next two rows of the table categorize hospitals according to their geographic location in FY14 (urban and rural). The second major grouping is whether the IRF is a freestanding facility or a part of a hospital unit, followed by a grouping for TRICARE network status. The fourth grouping is whether the IRF is a teaching facility and the fifth groups IRFs by Census division. The final grouping is by IRF ownership status.

The following discussion highlights some of the changes in allowed amounts among IRF classifications. Ninety-five percent of all TRICARE IRF admissions were to urban IRFs. Allowed amounts would have decreased by 45 percent for urban IRFs and 21 percent for rural IRFs.

TABLE 2—IMPACT OF TRICARE IRF RULE IN FY14

	Number of IRFs with TRICARE stays	Number of TRICARE discharges	Allowed per discharge (current policy)	Proposed policy allowed per discharge (medicare method)	Percent reduction in allowed amounts
All IRFs	568	2,603	$34,260	$19,129	44
Urban	523	2,473	34,944	19,257	45
Rural	45	130	21,248	16,687	21
Type	568	2,603	34,260	19,129	44
Freestanding	181	1,191	26,852	19,661	27
Hospital Unit	387	1,412	40,508	18,680	54
Network Status	568	2,603	34,260	19,129	44
Network	433	2,323	32,806	19,169	42
Non-Network	135	280	46,318	18,800	59
Teaching Status	568	2,603	34,260	19,129	44
Teaching	56	444	43,861	22,195	49
Non-Teaching	512	2,159	32,285	18,498	43
Region	568	2,603,	34,260	19,129	44
North East and Middle Atlantic	78	184	27,964	22,299	20
South Atlantic	47	242	27,730	16,486	41
East North Central	112	787	32,048	19,076	40
East South Central	44	122	33,838	15,707	54
West North Central	72	185	33,972	19,093	44
West South Central	109	611	33,749	18,714	45
Mountain	56	242	38,008	17,603	54
Pacific	50	230	51,600	24,108	53
Ownership	568	2,603	34,260	19,129	44
Proprietary	196	1,099	30,601	18,709	39
Government Owned	73	350	36,075	18,835	48
Voluntary	299	1,154	37,193	19,618	47

Source: FY14 TRICARE IRF Claims and FY16 Medicare Rate Setting File. Excludes claims with other health insurance (OHI).

Note: Excludes claims from 12 VA Hospitals (226 discharges), 4 Children's Hospitals (22 discharges), and 28 IRFs where we were unable to identify Medicare certification or sufficient Medicare data (78 discharges). We have combined the North East and Middle Atlantic states for the purpose of this impact analysis due to small sample size in the North East region.

The change in payment methodology would have resulted in a 54 percent reduction in the allowed amounts for IRFs that are part of a hospital unit. In comparison, freestanding IRF payments would have been reduced by 27 percent.

The change in IRF payment methodology would have a larger impact on TRICARE non-network IRFs than network IRFs because network IRFs currently offer a discount off billed charges while non-network IRFs do not. Allowed charges to non-network IRFs would have declined by 59 percent, in comparison to 42 percent for in-network hospitals. We found that network hospitals on average provide a 32 percent discount off billed charges for non-OHI TRICARE beneficiaries and that 89 percent of all TRICARE IRF discharges were in-network in FY14.

We also found that the change in IRF payment methodology would have a larger impact on teaching hospitals, where payments would have been reduced by 49 percent, in comparison to non-teaching hospitals, where payments would have been reduced by 43 percent. Approximately 83 percent of all TRICARE IRF discharges were from non-teaching IRF facilities.

IRFs in various geographic areas will be affected differently due to this change in payment methodology. The two regions with the largest number of TRICARE claims, the East North Central (787 discharges) and West South Central (611 discharges), would have had an average decrease of 40 and 45 percent in allowed charges respectively. IRFs in the North East and Middle Atlantic would have had the lowest reductions in allowed charges of 20 percent. The Mountain, East South Central, and Pacific regions would have had the highest reductions of between 53 and 54 percent.

Forty-two percent of all TRICARE IRF discharges in FY14 were in proprietary (for-profit) IRFs, and these facilities would have had their allowed amounts reduced by approximately 39 percent. The decline in allowed amounts for voluntary (not-for-profit) and government-owned IRFs would have been slightly more than proprietary hospitals (47 and 48 percent respectively).

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. In § 199.2, paragraph (b) is amended by:

■ a. Removing the definitions of "Hospital, long-term (tuberculosis, chronic care, or rehabilitation)" and "Long-term hospital care"; and

■ b. Adding the definitions of "Long Term Care Hospital *(LTCH)"* and "Inpatient Rehabilitation Facility *(IRF)* " in alphabetical order.

The additions read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Long Term Care Hospital (LTCH). A hospital that is classified by the Centers for Medicare and Medicaid Services (CMS) as a LTCH and meets the applicable requirements established by § 199.6(b)(4)(v) (which includes the requirement to be a Medicare participating provider).

* * * * *

Inpatient Rehabilitation Facility (IRF). A facility classified by CMS as an IRF and meets the applicable requirements established by Sec 199.6(b)(4)(xviii) (which includes the requirement to be a Medicare participating provider).

* * * * *

■ 3. In § 199.6, revise paragraphs (b)(4)(v) and (xvi), and add paragraph (xviii) to read as follows:

§ 199.6 TRICARE—authorized providers.

* * * * *

(b) * * *

(4) * * *

(v) Long Term Care Hospital (LTCH). LTCHs must meet all the criteria for classification as an LTCH under 42 CFR part 412, subpart O, as well as all of the requirements of this Part in order to be considered an authorized LTCH under the TRICARE program.

(A) In order for the services of LTCHs to be covered, the hospital must comply with the provisions outlined in paragraph (b)(4)(i) of this section. In addition, in order for services provided by such hospitals to be covered by TRICARE, they must be primarily for the treatment of the presenting illness.

(B) Custodial or domiciliary care is not coverable under TRICARE, even if rendered in an otherwise authorized LTCH.

(C) The controlling factor in determining whether a beneficiary's stay in a LTCH is coverable by TRICARE is the level of professional care, supervision, and skilled nursing care that the beneficiary requires, in addition to the diagnosis, type of condition, or degree of functional limitations. The type and level of medical services required or rendered is controlling for purposes of extending TRICARE benefits; not the type of provider or condition of the beneficiary.

* * * * *

(xvi) Critical Access Hospitals (CAHs). CAHs must meet all conditions of participation under 42 CFR 485.601 through 485.645 in relation to TRICARE beneficiaries in order to receive payment under the TRICARE program. If a CAH provides inpatient psychiatric services or inpatient rehabilitation services in a distinct part unit, the distinct part unit must meet the conditions of participation in 42 CFR 485.647, with the exception of being paid under the inpatient prospective payment system for psychiatric facilities as specified in 42 CFR 412.1(a)(2) or the inpatient prospective payment system for rehabilitation hospitals or rehabilitation units as specified in 42 CFR 412.1(a)(3). Upon implementation of TRICARE's IRF PPS in 199.14(a)(10), if a CAH provides inpatient rehabilitation services in a distinct part unit, the distinct part unit shall be paid under TRICARE's IRF PPS.

* * * * *

(xviii) Inpatient Rehabilitation Facility (IRF). IRFs must meet all the criteria for classification as an IRF under 42 CFR part 412, subpart B, and meet all applicable requirements established in this part in order to be considered an authorized IRF under the TRICARE program.

(A) In order for the services of inpatient rehabilitation facilities to be covered, the facility must comply with the provisions outlined in paragraph (b)(4)(i) of this section. In addition, in order for services provided by these facilities to be covered by TRICARE, they must be primarily for the treatment of the presenting illness.

(B) Custodial or domiciliary care is not coverable under TRICARE, even if rendered in an otherwise authorized inpatient rehabilitation facility.

(C) The controlling factor in determining whether a beneficiary's stay in an inpatient rehabilitation facility is coverable by TRICARE is the level of professional care, supervision, and skilled nursing care that the beneficiary requires, in addition to the diagnosis, type of condition, or degree of functional limitations. The type and level of medical services required or rendered is controlling for purposes of extending TRICARE benefits; not the type of provider or condition of the beneficiary.

* * * * *

■ 4. Section 199.14 is amended by:

■ a. Revising paragraphs (a)(1)(ii)(D)(*2*), (*3*) and (*4*), and (ii)(E);

■ b. Revising paragraph (a)(3)(i) introductory text; and

■ c. Adding new paragraphs (a)(9) and (10).

The revisions and additions read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *

(1) * * *

(ii) * * *

(D) * * *

(*2*) Inpatient Rehabilitation Facilities (IRF). Prior to implementation of the IRF PPS methodology described in paragraph (a)(10) of this section, an inpatient rehabilitation facility which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system.

(*3*) Psychiatric and rehabilitation units (distinct parts). Prior to implementation of the IRF PPS methodology described in paragraph (a)(10) of this section, a rehabilitation unit which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system. A psychiatric unit which is exempt from the Medicare prospective payment system is also exempt from the TRICARE DRG-based payment system.

(*4*) Long Term Care Hospitals. Prior to implementation of the LTCH PPS methodology described in paragraph (a)(9) of this section, a long term care hospital which is exempt from the Medicare prospective payment system is also exempt from the CHAMPUS DRG-based payment system.

* * * * *

(E) Hospitals which do not participate in Medicare. With the exceptions of CAHs, in addition to LTCHs and IRFs which must be Medicare-participating providers upon implementation of TRICARE's LTCH and IRF PPS, it is not required that a hospital be a Medicare-participating provider in order to be an authorized TRICARE provider. However, any hospital which is subject to the CHAMPUS DRG-based payment system and which otherwise meets CHAMPUS requirements but which is not a Medicare-participating provider (having completed a form HCA–1514, Hospital Request for Certification in the Medicare/Medicaid Program and a form HCFA–1561, Health Insurance Benefit Agreement) must complete a participation agreement with TRICARE. By completing the participation agreement, the hospital agrees to participate on all CHAMPUS inpatient claims and to accept the CHAMPUS-determined allowable amount as payment in full for these claims. Any hospital which does not participate in Medicare and does not complete a participation agreement with TRICARE will not be authorized to provide services to TRICARE beneficiaries.

* * * * *

(3) * * *

(i) For admissions on or after December 1, 2009, inpatient services provided by a CAH, other than services provided in psychiatric and rehabilitation distinct part units, shall be reimbursed at allowable cost (*i.e.*, 101 percent of reasonable cost) under procedures, guidelines, and instructions issued by the DHA Director, or designee. This does not include any costs of physicians' services or other professional services provided to CAH inpatients. Inpatient services provided in psychiatric distinct part units would be subject to the TRICARE mental health payment system. Inpatient services provided in rehabilitation distinct part units would be subject to billed charges. Upon implementation of TRICARE's IRF PPS, inpatient services provided in rehabilitation distinct part units would be subject to the TRICARE IRF PPS methodology in (a)(10) of this section.

* * * * *

(9) Reimbursement for inpatient services provided by an LTCH. (i) In accordance with 10 U.S.C. 1079(i)(2), TRICARE payment methods for institutional care shall be determined, to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. The TRICARE–LTC–DRG reimbursement methodology shall be in accordance with Medicare's Medicare Severity Long Term Care Diagnosis Related Groups (MS–LTC–DRGs) as found in regulation at 42 CFR part 412, subpart O. Inpatient services provided in hospitals subject to the Medicare LTCH Prospective Payment System (PPS) and classified as LTCHs and also as specified in 42 CFR parts 412 and 413 will be paid in accordance with the provisions outlined in sections 1886(d)(1)(B)(IV) and 1886 (m)(6) of the Social Security Act and its implementing Medicare regulation (42 CFR parts 412, 413, and 170) to the extent practicable. Under the above governing provisions, TRICARE will recognize, to the extent practicable, in accordance with 10 U.S.C. 1079(i)(2), Medicare's LTCH PPS methodology to include the relative weights, inpatient operating and capital costs of furnishing covered services (including routine and ancillary services), interrupted stay policy, short-stay and high cost outlier payments, the 25 percent threshold payment adjustment, site-neutral payments, wage adjustments for variations in labor-related costs across geographical regions, cost-of-living adjustments, payment adjustments associated with the quality reporting program, method of payment for preadmission services, and updates to the system.

(ii) Exemption. The TRICARE LTCH PPS methodology under this paragraph does not apply to hospitals in States that are reimbursed by Medicare and TRICARE under a waiver that exempts them from Medicare's inpatient prospective payment system or the TRICARE DRG-based payment system, respectively.

(10) Reimbursement for inpatient services provided by Inpatient Rehabilitation Facilities. (i) In accordance with 10 U.S.C. 1079(i)(2), TRICARE payment methods for institutional care shall be determined to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. The TRICARE IRF PPS reimbursement methodology shall be in accordance with Medicare's IRF PPS as found in 42 CFR part 412. Inpatient services provided in IRFs subject to the Medicare IRF prospective payment system (PPS) and classified as IRFs and also as specified in Subpart B of 42 CFR part 412 will be paid in accordance with the provisions outlined in section 1886(j) of the Social Security Act and its implementing Medicare regulation found at 42 CFR 412 subpart P to the extent practicable. Under the above governing provisions, TRICARE will recognize, to the extent practicable, in accordance with 10 U.S.C. 1979(i)(2), Medicare's IRF PPS methodology to include the relative weights, payment rates covering all operating and capitals costs of furnishing rehabilitative services adjusted for wage variations in labor-related costs across geographical regions, adjustments for 60 percent compliance threshold, teaching adjustment, rural adjustment, high-cost outlier payments, payment adjustments associated with the quality reporting program, and updates to the system. TRICARE will not adopt Medicare's low-income payment adjustment under TRICARE's IRF PPS.

(ii) Exemption. The TRICARE IRF PPS methodology under this paragraph does not apply to hospitals in States that are reimbursed by Medicare and TRICARE under a waiver that exempts them from Medicare's inpatient prospective payment system or the TRICARE DRG-based payment system, respectively.

* * * * *

Dated: August 24, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–20660 Filed 8–30–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0715]

RIN 1625–AA00

Safety Zone; Blasting, Delaware River

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the waters of the Tinicum Range, Eddystone Range, Chester Range, and Marcus Hook Range, in the Delaware River from December 1, 2016 to March 15, 2016. The safety zone would temporarily restrict vessel traffic from transiting or anchoring in a portion of the Delaware River while rock blasting, dredging, and rock removal operations are being conducted to facilitate the Delaware River Main Channel Deepening project for the main navigational channel of the Delaware River. This action is needed to protect personnel, vessels, and the marine environment from potential hazards created by rock blasting, dredging, and rock removal operations. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 30, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0715 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email MST1 Thomas Simkins, Sector Delaware Bay Waterways Management Division, U.S. Coast Guard; telephone 215–271–4889, email *Tom.J.Simkins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code
COTP	Captain of the Port

II. Background, Purpose, and Legal Basis

The Army Corps of Engineers (ACOE) is sponsoring a project, termed "The Deepening," in which dredging operations are taking place in the Delaware River and Bay navigational channel deepening the channel to 45 feet. The project goal is to maintain a minimum depth of 45 feet to accommodate larger vessel traffic entering the Sector Delaware Bay Zone. The upcoming portion of the project requires the deepening of the Delaware River from Tiniucm Range, south, through Marcus Hook Rang, in which the topography consist of mostly rock bottom. To satisfy the minimum project depth of 45 feet the ACOE has hired Great Lakes Dredging Company to perform rock blasting operations, dredging, and removal of rock in Tinicum Range, Eddystone Range, Chester Range, and Marcus Hook Range, in the Delaware River from December 1, 2016, to March 15, 2017. The Captain of the Port, Delaware Bay, has determined that potential hazards associated with rock blasting, dredging, and rock removal operations, will be a safety concern for anyone within 500 yards of rock blasting, dredging, and rock removal operations. This proposed rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the operational area.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 500-yard radius of rock blasting, dredging, and rock removal operations. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231; 33 CFR 1.05–1 and 160.5; and Department of Homeland Security Delegation No. 0170.1.

III. Discussion of Proposed Rule

This proposed rule would establish a safety zone from December 1, 2016, through March 15, 2017. The safety zone would cover all navigable waters in the Delaware River within 500 yards of vessels and machinery being used by personnel to conduct rock blasting, dredging, and rock removal. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while operations are being conducted.

For the duration of the project, in the vicinity of the rock blasting, rock removal, and dredging operation, one side of the main navigational channel will be closed due to the drill boat APACHE being unable to relocate for vessel traffic while conducting rock blasting and removal operations. Additionally there is a potential for blasted rock to be within the navigational channel causing a navigational safety hazard for vessels transiting the safety zone. Vessels wishing to transit the safety zone in the main navigational channel may do so if they can make satisfactory passing arrangements with drill boat APACHE, dredge TEXAS, or dredge NEW YORK in accordance with the navigational rules in 33 CFR subchapter E via VHF–FM channel 13 at least 30 minutes prior to arrival. If vessels are unable to make satisfactory passing arrangements with the drill boat APACHE, dredge TEXAS, or dredge NEW YORK they may request permission from the Captain of the Port, or his designated representative, on VHF–FM channel 16. All vessels must operate at the minimum safe speed necessary to maintain steerage and reduce wake.

No vessels may transit through the safety zone during times of explosives detonation. During rock blasting detonation, vessels would be required to maintain a 500 yard distance from the drill boat APACHE. The drill boat APACHE will make broadcasts, via VHF–FM channels 13 and 16, at 15 minutes, 5 minutes, and 1 minute prior to detonation, as well as a countdown to detonation on VHF–FM channel 16. The drill boat APACHE will also raise a red flag signifying when a detonation is occurring. The 500 yard radius will be secured by a contracted security vessel on either side of the blast area. Security vessels will ensure the blasting area is clear prior to explosive detonation. Sector Delaware Bay will ensure significant notice is given to the maritime community of dates and times of blasting via broadcast notice to mariners on VHF–FM channel 16. After every explosive detonation, a survey will be conducted to ensure the navigational channel is clear for vessels to transit. The drill boat APACHE will broadcast, via VHF–FM channels 13 and 16, when the survey has been completed and the channel is clear to transit. Vessels granted permission to transit through the safety zone must proceed as directed by the designated representative of the Captain of the Port, and must contact the drill boat APACHE, dredge TEXAS, or dredge NEW YORK on VHF–FM channel 13 to make satisfactory passing arrangements.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and traffic management of the safety zone. The Coast Guard does not anticipate any significant economic impact because the safety zone would be enforced in an area and in a manner that does not conflict with transiting commercial and recreational traffic, except for the short periods of time when explosive detonation evolutions are being conducted. The blasting detonations will not occur more than three times a day. At all other times, at least one side of the main navigational channel would be open for vessels to transit. Moreover, the Coast Guard will work in coordination with the pilots to ensure vessel traffic is limited during the times of detonation and Broadcast Notice to Mariners are made via VHF–FM marine channels 13 and 16 when blasting operations will occur.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to anchor in or transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone in force from December 1, 2016, through March 15, 2017, that prohibits entry within 500 yards of vessels and machinery being used by personnel conducting rock blasting, dredging, and rock removal operations within Tinicum Range, Eddystone Range, Chester Range, and Marcus Hook Range. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction M16475.1D. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T05–0715 under the undesignated center heading Fifth Coast Guard District to read as follows:

§ 165.T05–0715 Safety Zone; Blasting, Delaware River.

(a) *Regulated area.* The following area is a safety zone: all the waters of the Delaware River within 500 yards of the drill boat or dredges performing rock blasting, rock removal, and dredging operations, in the Delaware River between the southern end of Marcus Hook Range to the eastern end of Tinicum Range.

(b) *Regulations.* The general safety zone regulations in § 165.23 apply to the safety zone created by this temporary section, § 165.T05–0715.

(1) All vessels and persons are prohibited from entering into or moving within the safety zone unless authorized by the Captain of the Port, Delaware Bay, or by his designated representative.

(2) Vessels wishing to transit the safety zone, described in paragraph (a) of this section, in the main navigational channel, may do so if they can make satisfactory passing arrangements with the drill boat APACHE, dredge TEXAS, or dredge NEW YORK in accordance with the Navigational Rules in 33 CFR subchapter E via VHF–FM channel 13 at least 30 minutes prior to arrival. If vessels are unable to make satisfactory passing arrangements with the drill boat APACHE, dredge TEXAS, or dredge NEW YORK, they may request permission from the Captain of the Port, or his designated representative, on VHF–FM channel 16.

(3) No vessels may transit through the safety zone during times of explosives detonation. During rock blasting detonation, vessels are required to maintain a 500 yard distance from the drill boat APACHE. The drill boat APACHE will make broadcasts, via VHF–FM channels 13 and 16, at 15 minutes, 5 minutes, and 1 minute prior to detonation, as well as a countdown to detonation on VHF–FM channel 16. The drill boat APACHE will also raise a red flag signifying when a detonation is occurring. The 500 yard radius will be secured by contracted security vessel on either side of the blast area. Security vessel will ensure the blasting area is clear prior to explosive detonation. Sector Delaware Bay will ensure significant notice is given to the maritime community of dates and times of blasting via broadcast notice to mariners on VHF–FM channel 16.

(4) After every explosive detonation, a survey will be conducted to ensure the navigational channel is clear for vessels to transit. The drill boat APACHE will broadcast, via VHF–FM channels 13 and 16, when the survey has been completed and the channel is clear to transit. Vessels granted permission to transit through the safety zone must proceed as directed by the designated representative of the Captain of the Port and contact the drill boat APACHE on VHF–FM channel 13 to make satisfactory passing arrangements in accordance with the navigational rules in 33 CFR subchapter E.

(5) This section applies to all vessels except vessels that are engaged in the following operations: enforcing laws; servicing aids to navigation, and emergency response vessels.

(c) *Definitions.* As used in this section:

Captain of the Port Delaware Bay means the Commander, U.S. Coast Guard Sector Delaware Bay, Philadelphia, PA.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Delaware Bay to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This section will be effective from December 1, 2016, through March 15, 2017.

Dated: August 23, 2016.

Benjamin A. Cooper,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2016–20868 Filed 8–30–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0271]

RIN 1625–AA00

Safety Zone, Jacksonville Sea and Sky Spectacular; Atlantic Ocean, Jacksonville Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone on the waters of the Atlantic Ocean east of Jacksonville Beach, Florida during the Jacksonville Sea and Sky Spectacular. This safety zone will be enforced daily 10 a.m. to 4:30 p.m., from November 2 through November 6, 2016. This proposed rulemaking would prohibit persons and

vessels from being in the safety zone unless authorized by the Captain of the Port (COTP) Jacksonville or a designated representative. The Coast Guard invites your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 30, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0271 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Allan Storm, Sector Jacksonville, Waterways Management Division, U.S. Coast Guard; telephone (904) 714–7616, email *Allan.H.Storm@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code
COTP	Captain of the Port

II. Background, Purpose, and Legal Basis

On February 22, 2016, the City of Jacksonville submitted a marine event application to the Coast Guard for the Jacksonville Sea and Sky Spectacular that will take place from 10 a.m. to 4:30 p.m. on November 2 through November 6, 2016. The air show will consist of various flight demonstrations over the Atlantic Ocean, just offshore from Jacksonville Beach, FL. Over the years, there have been unfortunate instances of aircraft mishaps that involve crashing during performances at various air shows around the world. Occasionally, these incidents result in a wide area of scattered debris in the water that can damage property or cause significant injury or death to the public observing the air shows. The Captain of the Port (COTP) Jacksonville has determined that a safety zone is necessary to protect the general public from hazards associated with aerial flight demonstrations.

The purpose of the rulemaking is to ensure the safety of vessels and persons during the air show on the navigable waters of the Atlantic Ocean in Jacksonville Beach, FL. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone from 10 a.m. to 4:30 p.m. on November 2 through November 6, 2016. The safety zone will encompass all waters within an area approximately three miles parallel to the shoreline, and one half mile out into the Atlantic Ocean offshore from Jacksonville Beach, Florida. The duration of the zone is intended to ensure the safety of the public and these navigable waters during the aerial flight demonstrations. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text the Coast Guard is proposing appears at the end of the document.

IV. Regulatory Analyses

The Coast Guard developed this proposed rule after considering numerous statutes and Executive orders (E.O.s) related to rulemaking. A summary of the statutory analyses, analyses of E.O.s, and discussion of First Amendment rights of protestors is included below.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit around this safety zone which would impact a small designated area of the Atlantic Ocean for six and a half hours on each of the five days the air show is occurring. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 13175, Consultation and Coordination with

Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, the Coast Guard discusses the effects of this rule elsewhere in this preamble.

F. Environment

The Coast Guard analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone that will help protect the general public from hazards associated with aerial flight demonstrations occurring during the air show, and will be in effect from 10 a.m. to 4:30 p.m. on November 2 through November 6, 2016.

It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. A preliminary environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

Public participation is essential to effective rulemaking, and the Coast Guard will consider all comments and related materials received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

To view comments, as well as documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07–0271 to read as follows:

§ 165.T07–0271 Safety Zone; Jacksonville Sea and Sky Spectacular, Atlantic Ocean, Jacksonville Beach, FL.

(a) *Regulated Area.* The following regulated area is a safety zone located offshore from Jacksonville Beach, FL. All waters of the Atlantic Ocean encompassed within an imaginary line connecting the following points: starting at Point 1 in position 30°15′52.3″ N., 081°23′0.18″ W.; thence northwest to Point 2 in position 30°18′35.19″ N., 081°23′33.93″ W.; thence northeast to Point 3 in position 30°18′40.81″ N., 081°22′57.97″ W.; thence southeast to Point 4 in position 30°15′57.91″ N., 081°22′24.22″ W.; thence southwest back to origin. These coordinates are based on North American Datum 1983.

(b) *Definition.* The term "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Jacksonville in the enforcement of the regulated area.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Jacksonville or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Jacksonville by telephone at 904–714–7557, or a designated representative via VHF–FM radio on channel 16, to request authorization. If authorization is granted by the Captain of the Port Jacksonville or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Jacksonville or a designated representative.

(3) The Coast Guard will provide notice of the regulated area through Broadcast Notice to Mariners via VHF–FM channel 16 and by on-scene designated representatives.

(d) *Enforcement Period.* This rule is effective from November 2 through November 6, 2016 and will be enforced daily 10 a.m. to 4:30 p.m. on November 2 through November 6, 2016.

Dated: August 23, 2016.

L.C. Parrales,

Commander, U.S. Coast Guard, Acting Captain of the Port Jacksonville.

[FR Doc. 2016–20923 Filed 8–30–16; 8:45 am]

BILLING CODE 9110–04–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2016–11; Order No. 3489]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to analytical principles relating to periodic reporting (Proposal Three). This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 11, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Proposal Three
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IV. Ordering Paragraphs

I. Introduction

On August 22, 2016, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate an informal rulemaking proceeding to consider changes in analytical principles used to prepare the Postal Service's periodic reports.[1] The Petition identifies the proposed changes filed in this docket as Proposal Three.

II. Proposal Three

Proposal Three relates to the design and operation of the In-Office Cost System (IOCS). The proposal concerns changes in the IOCS city carrier sampling methodology and the development of city carrier costs. The Postal Service states that the proposal utilizes census data from the Time and Attendance Collection System (TACS) and the Delivery Operations Information System (DOIS) to develop a new cluster sampling approach. Petition, Proposal Three at 1. This new sampling approach permits data collectors to take on-site readings in the mornings when city carriers conduct the majority of their in-office work. *Id.* The Postal Service states that the availability of TACS census data provides the opportunity to significantly reshape the sampling design. *Id.* at 2. The Postal Service states that the primary objective of this proposal is to replace the current method of obtaining data via telephone readings with on-site readings. *Id.* at 15. In support of its Petition, the Postal Service has attached a public library reference, USPS–RM2016–11/1, and a non-public library reference, USPS–RM2016–11/NP1.[2]

III. Notice and Comment

The Commission establishes Docket No. RM2016–11 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's Web site at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Three no later than October 11, 2016. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2016–11 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), filed August 22, 2016.

2. Comments by interested persons in this proceeding are due no later than October 11, 2016.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–20930 Filed 8–30–16; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60 and 62

[EPA–HQ–OAR–2016–0033; FRL–9951–72–OAR]

RIN 2060–AS84

Clean Energy Incentive Program Design Details; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: On June 30, 2016, the Environmental Protection Agency (EPA) proposed a rule titled, "Clean Energy Incentive Program Design Details." The EPA is extending the comment period on the proposed rule, which was scheduled to close on September 2, 2016, by 60 days until November 1, 2016. The EPA is making this change to allow for requested tribal consultation in response to the proposed rule.

DATES: The public comment period for the proposed rule published in the **Federal Register** on June 30, 2016 (81 FR 42940), and extended at 81 FR 47325 (July 21, 2016) is being further extended. Written comments must be received on or before November 1, 2016.

ADDRESSES: The EPA has established a docket for the proposed rulemaking (available at *http://www.regulations.gov*). The Docket ID No. is EPA–HQ–OAR–2016–0033. Information on this action is posted at *https://www.epa.gov/cleanpowerplan/clean-energy-incentive-program.* Submit your comments, identified by the appropriate Docket ID No., to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make.

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[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), August 22, 2016 (Petition).

[2] Notice of Filing of USPS–RM2916–11/1, USPS–RM2016–11/NP1, and Application for Nonpublic Treatment, August 22, 2016.

For additional submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html.*

FOR FURTHER INFORMATION CONTACT: For additional information on this action, contact Dr. Tina Ndoh, Sector Policies and Programs Division, Office of Air Quality Planning and Standards (D243–04), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2750; email address: *ndoh.tina@epa.gov.*

SUPPLEMENTARY INFORMATION: A number of tribes working on comments for the Clean Energy Incentive Program (CEIP) Design Details proposed rule (81 FR 42940; June 30, 2016) have asked for additional consultation to better understand the issues related to the interaction between state plans and projects on tribal land that may qualify for the CEIP. Because of the interest of a number of tribes, the EPA believes it is appropriate to extend the comment period to allow for the requested tribal consultations and to provide tribes time to incorporate any information from those consultations in their comments. The EPA extended the initial comment period at 81 FR 47325 (July 21, 2016). The EPA is further extending the comment period for the CEIP Design Details proposal by 60 days, to November 1, 2016.

Dated: August 25, 2016.

Stephen Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2016–20898 Filed 8–30–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 390

[Docket No. FMCSA–2012–0103]

RIN 2126–AB90

Lease and Interchange of Vehicles; Motor Carriers of Passengers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of intent.

SUMMARY: FMCSA announces its intent to issue a rulemaking concerning revisions to its May 27, 2015, final rule titled "Lease and Interchange of Vehicles; Motor Carriers of Passengers." The Agency received numerous petitions for reconsideration of the final rule and determined that amendments should be considered in response to some of the petitions. The aspects of the 2015 final rule to be reconsidered are discussed later in this document. In addition, FMCSA will hold a roundtable discussion on the scope of the issues to be addressed in the forthcoming rulemaking. The meeting will be public and will seek public input regarding the assignment of responsibility for safety violations to the correct party. Individuals with diverse experience, expertise, and perspectives are encouraged to attend. If all comments have been exhausted prior to the end of the session, the session may conclude early. The Agency intends to complete any regulatory action(s) taken in response to the petitions before January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, (202) 385–2428, *loretta.bitner@dot.gov,* Office of Enforcement and Compliance. FMCSA office hours are from 9 a.m. to 5 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

On May 27, 2015, FMCSA published a final rule concerning the lease and interchange of passenger-carrying commercial motor vehicles (CMVs) (80 FR 30164). The purpose of the rule is to identify the motor carrier operating a passenger-carrying CMV that is responsible for compliance with the Federal Motor Carrier Safety Regulations (FMCSRs) and ensure that a lessor surrenders control of the CMV for the full term of the lease or temporary exchange of CMV(s) and driver(s). The Agency received 37 petitions for reconsideration which have been filed in the public docket referenced above. Upon review of these requests, FMCSA concluded that some have merit. FMCSA, therefore, extended the compliance date of the final rule from January 1, 2017, to January 1, 2018 (82 FR 13998; March 16, 2016) to allow the Agency time to complete its analysis and amend the rule where necessary.

Petitioners made the following substantive arguments, which the Agency will address in subsequent rulemaking.

General Objections

The petitioners generally argued that FMCSA has taken a regulatory scheme from the trucking industry and applied it to the bus industry, which has a vastly different operating structure and liability regimen. Moreover, the application of these truck regulations to the bus industry offers no additional protection to the public from illegal or unsafe bus operators. Instead, the final rule simply adds administrative costs and reduces operational flexibility for bus operators.

Petitioners further stated that the final rule creates an economic and regulatory burden on passenger carriers that already operate safely and have a high degree of compliance. Some of the petitioners argue that those lease requirements will not stop carriers that choose to violate the regulations, yet will burden those who already operate safely and compliantly.

A petitioner stated that while it supports efforts to identify and address chameleon carriers or carriers that may try to operate under the cloak of another carrier, the final rule does not accomplish this goal and in fact provides a roadmap for irresponsible carriers to operate legally under the authority of another carrier.

One carrier stated that it had identified several instances where the final rule lacks sufficient clarity to enable it to comply, and that these issue areas have an effect on all of its operations. The final rule also adds administrative costs and reduces operational flexibility for charter and tour bus operations, which will, in the end, reduce connectivity and transportation options for the traveling public.

Another carrier argued that the three 2008 crashes cited in the September 20, 2013 notice of proposed rulemaking (NPRM) involved a tire failure, driver error, and an insurance issue (78 FR 57822), and that nothing in the final rule would have prevented any of these crashes. The commenter also named two insurance companies that have restrictions in their policies that prohibit the use of non-owned equipment and non-employed drivers, which were major concerns of the NPRM.

Many of the objections raised by petitioners can be addressed by providing additional explanation. However, some of the issues discussed below may require regulatory changes; they fall into four major categories.

Four Changes Under Consideration

(1) Exclusion of "chartering" (*i.e.,* subcontracting) from the leasing

requirements. The 2015 rule merged the concepts of leasing with "chartering" (subcontracting). Carriers routinely subcontract work to other registered carriers to handle demand surges, emergencies, or events that require more than the available capacity. Subcontractors with their own operating authority have traditionally assumed responsibility for their own vehicles/drivers. Under the 2015 rule, however, a passenger carrier that subcontracted work to another carrier would be responsible for that second carrier's compliance with the regulations. Petitioners claim that making a carrier responsible for the subcontractor's vehicles, drivers, and liability would make most short-term subcontracts impossible.

(2) Amending the CMV requirements for the location of temporary markings for leased/interchanged vehicles. The petitioners argued that the frequent marking changes needed during leases or interchanges would be impractical and unnecessary because the information required is recorded on the driver's records of duty status for roadside inspectors and safety investigators to review; carriers will have to depend completely on their drivers to properly change vehicle markings dozens of times per day in remote locations; and it is unlikely that a member of the public is going to understand the significance of the markings in the event that he or she focuses on the temporary "operated by" markings rather than the permanent markings on the bus representing the vehicle owner.

(3) Changing the requirement that carriers notify customers within 24 hours when they subcontract service to other carriers. Petitioners argued that a 24-hour deadline is impractical because if an emergency maintenance issue occurs, it may not be possible to notify the customer in a timely manner, particularly if the issue occurs on the weekend, when the customer's offices are closed, and the start time is before the customer's Monday opening time.

(4) Expanding the 48-hour delay in preparing a lease to include emergencies when passengers are not actually on board a bus. Sometimes events requiring a replacement vehicle might occur when there are no passengers on a vehicle, such as when Amtrak or airline service is suspended or disrupted and buses are needed to transport stranded passengers. A bus operator contracted to provide the rescue service might need to obtain additional drivers and vehicles from other carriers to meet the demand. There might be a last minute maintenance or mechanical issue, or driver illness, that arises late in the evening or during the night (such as on a multi-day charter or tour trip), or just prior to picking up a group for a charter or scheduled service run.

FMCSA Decision

FMCSA plans to issue a rulemaking notice to address the four areas of concern listed above. The Agency believes that less burdensome regulatory alternatives that would not adversely impact safety could be adopted before the January 1, 2018. The Agency denies the petitions for reconsideration of all other aspects of the final rule. These petitions either would have impaired the purpose of the final rule or did not include practical alternatives.

The Agency will provide petitioners with written notification of these decisions at a later date.

Public Roundtable

FMCSA will hold a public roundtable to discuss the four issue areas discussed above. The public will have an opportunity to speak about these issues and provide the Agency with information on how to address them. All public comments will be placed in the docket of this rulemaking. Details concerning the schedule and location of the roundtable, as well as procedural information for participants, will follow in a subsequent **Federal Register** notice.

Issued on: August 19, 2016.

T.F. Scott Darling, III,

Administrator.

[FR Doc. 2016–20609 Filed 8–30–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2014–0058; FXES11130900000C2–167–FF09E42000]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To Delist the Coastal California Gnatcatcher

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to remove the coastal California gnatcatcher (*Polioptila californica californica*) from the Federal List of Endangered and Threatened Wildlife (List) under the Endangered Species Act of 1973, as amended. After review of the best available scientific and commercial information, we find that delisting the coastal California gnatcatcher is not warranted at this time.

DATES: The finding announced in this document was made on August 31, 2016.

ADDRESSES: This finding, as well as supporting documentation we used in preparing this finding, is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2014–0058. Supporting documentation we used in preparing this finding will also be available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: G. Mendel Stewart, Field Supervisor, Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, CA 92008; by telephone at 760–431–9440; or by facsimile at 760–431–5901. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Under the Endangered Species Act of 1973, as amended (ESA or Act; 16 U.S.C. 1531 *et seq.*), we administer the Federal Lists of Endangered and Threatened Wildlife and Plants, which are set forth in title 50 of the Code of Federal Regulations in part 17 (50 CFR 17.11 and 17.12). Under section 4(b)(3)(B) of the Act, for any petition that we receive to revise either List by adding, removing, or reclassifying a species, we must make a finding within 12 months of the date of receipt if the petition contains substantial scientific or commercial information supporting the requested action. In this finding, we will determine that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted, but the immediate proposal of a regulation is precluded by other pending proposals to determine whether any species are endangered species or threatened species and expeditious progress is being made to add or remove qualified species from the Lists. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Previous Federal Actions

Since the coastal California gnatcatcher was first identified as a category 2 candidate species in 1982, it has been the subject of numerous **Federal Register** publications. We published a final rule to list *Polioptila californica californica* as a threatened species under the Act on March 30, 1993 (58 FR 16742), and we affirmed that determination in 1995 (60 FR 15693; March 27, 1995). Critical habitat for the subspecies was first established via a final rule that published on October 24, 2000 (65 FR 63680), and a revised final critical habitat rule was published on December 19, 2007 (72 FR 72010). The most recent Federal action prior to 2014 was our 2011 90-day finding on a petition to delist the coastal California gnatcatcher (76 FR 66255; October 26, 2011). We concluded at that time that the petition did not present substantial scientific or commercial information to indicate that delisting the coastal California gnatcatcher may be warranted (76 FR 66255; October 26, 2011). A summary of all previous Federal actions can be found at *http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=B08X.*

Species Information

The coastal California gnatcatcher (*Polioptila californica californica*) is a member of the avian family Polioptilidae (Chesser *et al.* 2010, p. 736). The bird's plumage is dark blue-gray above and grayish-white below. The tail is mostly black above and below. The male has a distinctive black cap, which is absent during the winter. Both sexes have a distinctive white eye-ring. This subspecies occurs primarily in or near vegetation categorized as coastal scrub, including coastal sage scrub. This vegetation is typified by low (less than 3 feet (ft) (1 meter (m)), shrub, and sub-shrub species that are often drought-deciduous (O'Leary 1990, p. 24; Holland and Keil 1995, p. 163; Rubinoff 2001, p. 1,376). Within the United States, the subspecies is restricted to coastal southern California from Ventura and San Bernardino Counties, south to the Mexican border. Within Mexico, its range extends from the U.S.-Mexico border into coastal Baja California south to approximately El Rosario, Mexico, at about 30 degrees north latitude (Grinnell 1926, p. 499; AOU 1957, p. 451; Miller *et al.* 1957, p. 204; Atwood 1991, p. 127; Phillips 1991, pp. 25–26; Atwood and Bontrager 2001, p. 3).

In our 2010 5-year review, we reported an estimate of 1,324 gnatcatcher pairs over an 111,006-acre (ac) (44,923-hectare (ha)) area on lands owned by city, county, State, and Federal agencies (public and quasi-public lands) of Orange and San Diego Counties (Service 2010, p. 8). We indicated that this study sampled only a portion of the U.S. range of the subspecies (the coastal regions), and that it was limited to 1 year (Winchell and Doherty 2008, p. 1,324). Standardized, rangewide population trends and occupancy estimates for the coastal California gnatcatcher (within the United States or Mexico) are not available at this time given the limited and incomplete survey information as well as the variability in the survey methods and reporting.

Since the publication of the 2010 5-year review, we have received the following results from limited surveys of the coastal California gnatcatcher within the U.S. portion of the range:

(1) 25 nests (with 11 successes out of 29 nesting attempts) within the Western Riverside County Multi-Species Habitat Conservation Plan (Western Riverside County MSHCP) for the year 2014 in eight of the plan's designated core areas (Biological Monitoring Program 2015, p. 8);

(2) 122 pairs and 33 single males (155 territories) within the City of Carlsbad (under the San Diego County Multiple Habitat Conservation Plan (San Diego County MHCP) in 2013, an increase of 28 territories from 2010 despite little change in survey area (City of Carlsbad 2013, p. 2);

(3) for Orange County, 12.7 percent occupancy within the Central Reserve and 34.3 percent occupancy in the Coastal Reserve (plus 17 other incidental observations) (Leatherman Bioconsulting 2012, p. 5); and

(4) 436 occupied sites for the coastal California gnatcatcher on Marine Corps Base Camp Pendleton (Camp Pendleton) (San Diego County) in 2014, including 122 territorial males, 283 pairs, and 31 family groups, with an additional 53 transient individuals identified (Tetra Tech 2015, p. ii). We will continue to work with our partners to gather data on coastal California gnatcatcher populations and trends.

Since listing, we have updated information regarding the range of the subspecies. In our 2010 5-year review (Service 2010, pp. 6, 8; Table 1), we presented our estimate of the existing range of the coastal California gnatcatcher at that time. We also updated the extent of the subspecies' range in Baja California, Mexico, using the coastal sage scrub vegetation map prepared by Rebman and Roberts (2012, p. 22) and observations of California gnatcatchers (all subspecies of *Polioptila californica*) (in Baja California (*www.ebird.org;* accessed December 15, 2015). This information is combined in the range map shown in Figure 1. We currently estimate 56 percent of the range is in the United States and 44 percent of the range is in Baja California, Mexico.

For additional information on the general biology and life history of the coastal California gnatcatcher, please see our most recent 5-year status review (Service 2010), available at the following Web sites: *http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=B08X* and *http://www.fws.gov/carlsbad/.*

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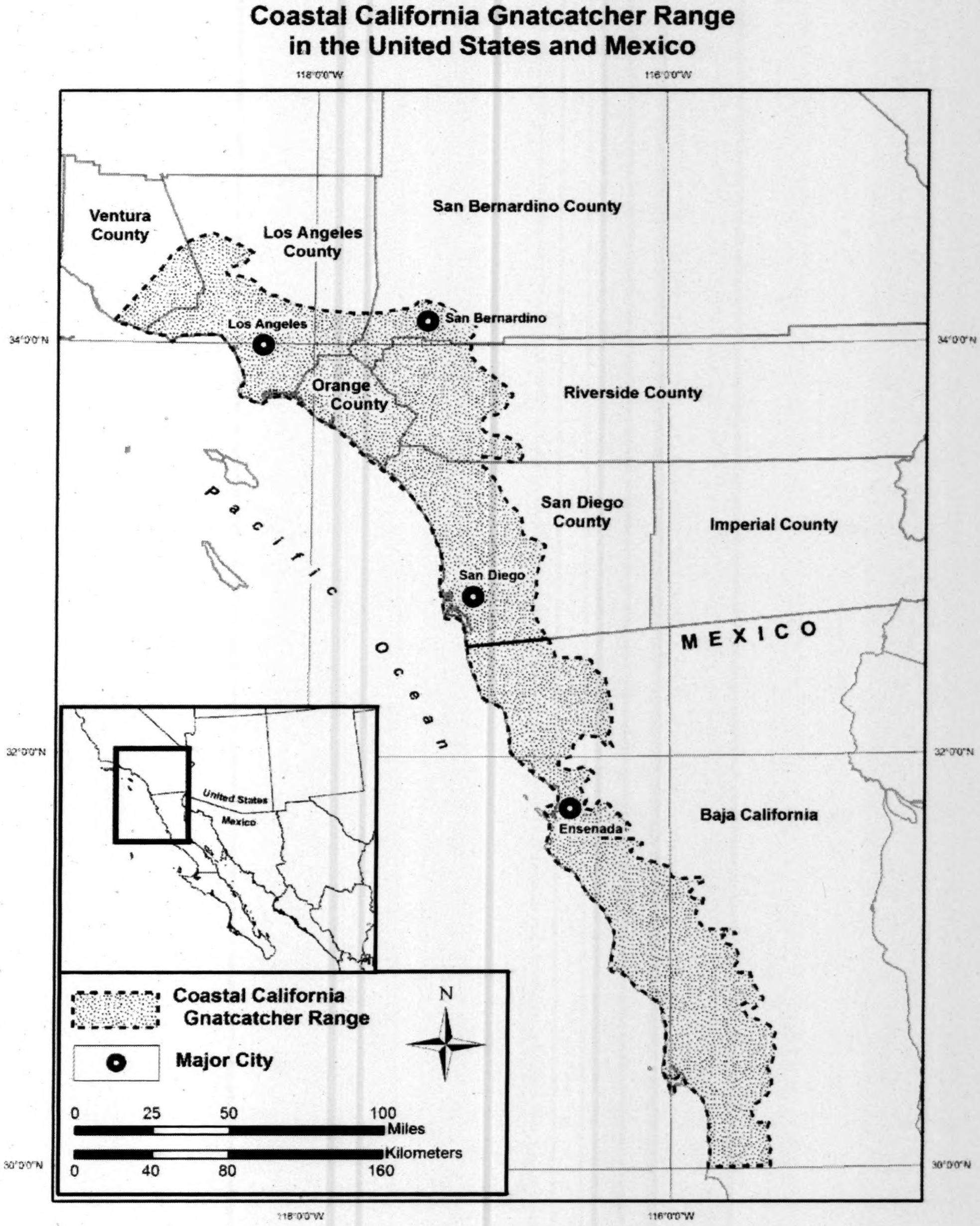
Coastal California Gnatcatcher Range in the United States and Mexico

118°0'0"W
116°0'0"W
34°0'0"N
32°0'0"N
30°0'0"N
Ventura County
Los Angeles County
San Bernardino County
Los Angeles
San Bernardino
Orange County
Riverside County
San Diego County
Imperial County
San Diego
Pacific Ocean
MEXICO
Ensenada
Baja California
United States
Mexico
Coastal California Gnatcatcher Range
Major City
N
0 25 50 100 Miles
0 40 80 160 Kilometers

Figure 1—Current range of the coastal California gnatcatcher, based on information from our 2010 5-year review (Service 2010, pp. 6, 8; Table 1), the coastal sage scrub vegetation map prepared by Rebman and Riley (2012, p. 22), and observations of California gnatcatchers reported in Baja California, Mexico (www.ebird.org; accessed December 15, 2015).

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Petition History

On May 29, 2014, we received a combined petition from the Center for Environmental Science, Accuracy, and Reliability; Coalition of Labor, Agriculture and Business; Property Owners Association of Riverside County; National Association of Home

Builders; and the California Building Industry Association (collectively, petitioners), requesting that the coastal California gnatcatcher be removed from the Federal List of Endangered and Threatened Wildlife (List) under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioners, as required in 50 CFR 424.14(a).

The factors for listing, delisting, or reclassifying species are described at 50 CFR 424.11. We may delist a species only if the best scientific and commercial data available substantiate that it is neither endangered nor threatened. Delisting may be warranted as a result of: (1) Extinction; (2) recovery; or (3) a determination that the original scientific data used at the time the species was listed, or interpretation of that data, were in error.

The petition did not assert that the coastal California gnatcatcher is extinct, nor do we have information in our files indicating that the coastal California gnatcatcher is extinct. The petition did not assert that the coastal California gnatcatcher has recovered and is no longer an endangered species or threatened species, nor do we have information in our files indicating the coastal California gnatcatcher has recovered (further detail on the status of the coastal California gnatcatcher is presented in the *Summary of the Five Factors* section below). The petition also did not contain any information regarding threats to the coastal California gnatcatcher.

The petition asserts that the original scientific data used at the time the species was classified were in error and that the best available scientific data show no support for the taxonomic recognition of the coastal California gnatcatcher as a distinguishable subspecies (Thornton and Schiff 2014, p. 1). The petition's assertions are primarily based on the results of genetic and ecological analyses published in Zink *et al.* (2013). The petition maintains that, based on this new information, the Service cannot continue to rely on morphological measurements to determine whether the coastal California gnatcatcher is a valid (distinguishable) subspecies (Thornton and Schiff 2014, pp. 31–32).

The petition asserts that the morphological information originally used to distinguish the subspecies is flawed, citing published and unpublished critiques, alternative analyses, and other interpretations of morphological characteristics of California gnatcatchers (Thornton and Schiff 2014, pp. 14–21). The petition also contends that available genetic data do not support the coastal California gnatcatcher as a distinguishable subspecies (Thornton and Schiff 2014, p. 28). As evidence, the petition cites two published scientific articles in particular, Zink *et al.* (2000) and Zink *et al.* (2013), which were included as part of the petition. The petition asserts that these two studies "constitute the best available scientific data" (Thornton and Schiff 2014, p. 28) regarding the subspecific status of the coastal California gnatcatcher.

The petition discusses the results of both Zink *et al.* (2000) and Zink *et al.* (2013). Zink *et al.* (2000) examined variation within the mitochondrial DNA (mtDNA) control region and three mtDNA genes of the California gnatcatcher species as a whole and concluded that the genetic information did not support recognition of infraspecific taxa (subspecies) in the California gnatcatcher, including the coastal California gnatcatcher subspecies (Thornton and Schiff 2014, pp. 20–23). The petition further asserts that the genetic analysis presented in Zink *et al.* (2013, entire), based on eight different nuclear markers or loci and a reduced data set from Zink *et al.* (2000, entire), did not identify geographic groupings that corresponded with any previously recognized subspecies (Thornton and Schiff 2014, p. 28). The petition states that the nuclear DNA analysis in Zink *et al.* (2013) is consistent with a conclusion that the range of the California gnatcatcher has recently expanded from southern Baja California and that the species "is not divisible into discrete, listable units" (Thornton and Schiff 2014, p. 29).

The petition also provides results from an ecological niche model from Zink *et al.* (2013, pp. 453–454). The study presented results from niche divergence models constructed for California gnatcatchers represented in mesic coastal sage scrub ("northern population") versus southern populations. The petition asserts that the model results indicate that the two groups do not exhibit significant niche divergence if the backgrounds of each environment are taken into account; it further states that the results from the ecological niche model support the petition's assertions that there is no valid taxonomic subdivision of the California gnatcatcher (Thornton and Schiff 2014, pp. 29–30). The petition concludes that the best available data indicate that the California gnatcatcher (the species as a whole) "is not divisible into discrete, listable units, but instead is a single historical entity throughout its geographic range" (Thornton and Schiff 2014, p. 32).

On December 31, 2014, we published in the **Federal Register** a 90-day finding (79 FR 78775) that the petition presented substantial information indicating that delisting may be warranted. With publication of the finding, we initiated a review of the status of the subspecies. We requested further information from the public on issues related to the coastal California gnatcatcher such as: Taxonomy; biology; new morphological or genetic information; consideration of the coastal California gnatcatcher as a distinct population segment (DPS); and information on the methods, results, and conclusions of Zink *et al.* (2000; 2013). In our status review below, we first examine whether the coastal California gnatcatcher is a valid subspecies, and thus a "species" as defined in section 3 of the Act. According to section 3(16) of the Act, we may list any of three categories of vertebrate animals: A species, subspecies, or a distinct population segment of a vertebrate species of wildlife. We refer to each of these categories as a "listable entity." If we determine that there is a species, or "listable entity," for the purposes of the Act, our status review next evaluates whether the species meets the definitions of an "endangered species" or a "threatened species" because of any of the five listing factors established under section 4(a)(1) of the Act.

In response to our information request associated with the status review of the subspecies, we received more than 39,000 letters. Most responders submitted form letters that opposed delisting of the coastal California gnatcatcher. Some submitted additional reports and references for our consideration. New information submitted included survey and trend data for localized areas, information related to effectiveness of regulatory mechanisms, information on restoration efforts, and information on threats to the subspecies and its habitat in the United States and in Mexico.

Additionally, multiple parties submitted critical analyses of information presented in the petition and in Zink *et al.* (2013), including a then "in press" (prepublication) scientific paper that was subsequently published in the journal *The Auk: Ornithological Advances* (McCormack and Maley 2015) that disputed the methods and results presented in Zink *et al.* (2013). We received several responses from members of the scientific community, many of which provided critiques of the methods and interpretations of Zink *et al.* (2013), including critiques of the statistical analyses of the information presented, the selection and number of loci used in the genetic analyses, the methods and interpretation of the niche model, and the conclusion by Zink *et al.* (2013) that a lack of detection of genetic structure necessarily meant a lack of taxonomic distinctiveness (Andersen 2015, pers. comm.; Cicero 2015, pers. comm.; Fallon 2015, pers. comm.; Patten 2015, pers. comm.). We also received reanalyses of the genetic data used by Zink *et al.* (2013) (Andersen 2015, pers. comm.; McCormack and Maley 2015).

One commenter expressed support for the petition's arguments and the conclusions reached by Zink *et al.* (2013) and dismissed the findings of McCormack and Maley (2015) (Ramey 2015, pers. comm.). We received two responses from Zink dated March 2, 2015, and June 8, 2015 (Zink 2015a, pers. comm.; Zink 2015b, pers. comm.), and we received a response from one of the petitioners dated March 2, 2015 (Thornton 2015, pers. comm.), that directly addressed the critiques submitted by many of the other responders. These additional responses and additional supporting materials are available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2014–0058.

Given the diverse and conflicting information submitted by the public and members of the scientific community in response to our request for information (79 FR 78775; December 31, 2014), we convened a scientific review panel. Through a Science Advisory Services contract process, the Service contracted Amec Foster Wheeler Infrastructure and Environment, Inc. (hereafter Amec Foster Wheeler) to assemble a panel of independent experts to provide individual input on the available data concerning the subspecies designation of the coastal California gnatcatcher. Amec Foster Wheeler selected six panelists in accordance with peer review and scientific integrity guidelines from the Office of Management and Budget's *Final Information Quality Bulletin* (OMB 2004). The selected panelists each had between 19 and 35 years of experience in their respective fields, which included avian conservation, conservation genetics, taxonomy, population genetics, and systematics. An experienced facilitator with expertise in genetics and genetic techniques was also selected by Amec Foster Wheeler to assist and guide the panelists in their discussions during a 2-day workshop. Additional details regarding the selection of the panelists and their qualifications are available in the Final Workshop Review Report for the California Gnatcatcher Facilitated Science Panel Workshop (hereafter "science panel report") (Amec 2015, pp. 2–3, and Appendix D). This report is available as a supporting document we used in preparing this finding on the Internet at *http://www.regulations.gov* at Docket Number FWS–R8–ES–2014–0058. Conflict of interest forms were submitted by each panelist. The Service was not involved in any portion of the selection process, nor were we aware of the panelists' identities prior to the workshop.

Prior to the workshop, the Service prepared a list of relevant literature and **Federal Register** documents related to the science and listing history of the coastal California gnatcatcher. The panelists requested that we provide summaries of the subspecies' listing history, taxonomy, the Service's listable entity and DPS policies, and a summary of public comments. All documents were relayed to the panelists through the Amec Foster Wheeler Project Manager. A complete list of information and references provided is available in the workshop science panel report (Amec 2015, Appendix B).

The workshop was held at the Carlsbad Fish and Wildlife Office on August 17–18, 2015. The purpose of the workshop was to provide a forum for the panelists to review the summary documents provided and to discuss the issues relevant to the taxonomic and systematic issues for the subspecies (see workshop agenda in Amec 2015, p. A–1). During the contracting process, the Service developed a Statement of Work with five suggested questions that the panelists consider during the workshop regarding the taxonomy and systematics issues related to the coastal California gnatcatcher. These are provided in the Amec Foster Wheeler science panel report (Amec 2015, p. A–2). Service personnel did not participate in the workshop discussions or interact with the panelists, with the exception of a brief question-and-answer session on the second day when the panelists requested clarification related to previous Federal actions and Service policies (for example, the DPS policy).

In our Statement of Work, we indicated that the panelists (to be selected by Amec) would include avian genetic and taxonomic researchers as well as experts in avian phylogeographic studies. We also requested that the Contractor would have sufficient experience and understanding in the field of genetics in order to be able to lead and facilitate the discussion of the panelists. The proposal for the facilitated expert panel workshop submitted by Amec to the Service on May 5, 2015 (revised May 13, 2015), included a summary of the six panelists' experience (ranging from 19 to 35 years each) and general areas of expertise in the fields of molecular genetics, avian conservation genetics, avian systematics, conservation genetics, population genetics, and avian molecular genetics. One of the panelists selected by Amec was subsequently replaced due to a scheduling conflict. The proposal also included the qualifications of the facilitator and Amec's Project Manager. We received the panelists' individual curriculum vitae with the draft and final workshop reports. After reviewing the panelists' individual curriculum vitae, we confirmed the six panelists are qualified experts in the fields of molecular genetics, avian conservation genetics, avian systematics, conservation genetics, population genetics, and avian molecular genetics. The Project Manager also noted in Amec's proposal that several panelists had requested that their individual memoranda be presented in the final report without attribution. Although we did not have knowledge of the attribution of the individual memorandums to the six panelists, we determined that all panelists are subject matter experts qualified to evaluate the scientific information presented in the petition. Additional details about the workshop process and the panelist discussions are available in the science panel summary report (Amec 2015, pp. 5–7).

After the workshop, each panelist individually prepared a memorandum that addressed topics relevant to the scientific information presented in the petition (for example, Zink *et al.* 2013) and to the subspecific taxonomic status of the coastal California gnatcatcher. We discuss the key information from those memoranda in the following section. In discussing specific supporting information and other comments presented in the individual memoranda, we refer to the panelists and their memos by the numbers randomly assigned to them by Amec Foster Wheeler (Panelist 1, Panelist 2, etc.) or to the Amec Workshop Report page number (Amec 2015).

Key Information From the Science Panel Memoranda

The panelists were not asked to reach a consensus. However, all six panelists found that the arguments presented by Zink *et al.* (2000; 2013) were not convincing, and that the coastal California gnatcatcher is currently a valid (distinguishable) subspecies. Panelists made the following points:

- The criteria used to distinguish subspecies should include multiple lines of evidence, such as morphology, genetics, and ecology. As such, the use of phylogenetic criteria alone to distinguish (or fail to distinguish) the coastal California gnatcatcher as a subspecies is not appropriate.
- Patterns of differentiation should be applied based on proposed mechanisms of evolution and the geologic age at which those events occurred, and the appropriate tools must be applied to adequately test those hypotheses. Based on the biogeographic history of the region, the infraspecific divergence in the coastal California gnatcatcher is of recent origin (less than 12,000 years before present, see Zink *et al.* 2000, 2013); therefore, the subspecies is likely in the earliest stages of adaptive differentiation.
- Relatedly, the amount of divergence in a small number of neutral genetic markers (genes that are not subject to selective pressures and, therefore, change slowly over time through accumulation of random changes) is likely to be small and unlikely to demonstrate genetic differences between subspecies.
- The genetic analyses conducted by Zink *et al.* (2000, 2013) contain insufficient information to detect subspecies limits. The panelists stated that the methods of Zink *et al.* (2000; 2013) for analyzing the data were not appropriate for detecting recent, infraspecific divergence, as likely occurred in the case of the coastal California gnatcatcher.
- Panelists generally concurred that genetic studies that examine neutral genetic markers should not overturn existing subspecies boundaries, especially when divergence is not detected.

Panelists provided detailed information on the limitations of the conclusions that can be made based on the analyses presented in Zink *et al.* (2013) and other currently available information. In addition, the panelists concluded that two prior peer reviews had addressed the morphological data on the coastal California gnatcatcher, and that there was no new information in the materials provided or in the petition regarding the morphology of the coastal California gnatcatcher. Several panelists also provided recommendations for additional analyses and areas of research for future taxonomic studies.

In late 2015, Zink *et al.* submitted to the Service what was then an in-press manuscript (Zink 2015c, pers. comm.) that was subsequently published in *The Auk: Ornithological Advances* in January 2016 (available electronically December 2015). The article (Zink *et al.* 2016) presented additional interpretation and analysis of the data and models from Zink *et al.* (2013). Zink *et al.* (2016) responded to the criticisms of McCormack and Maley (2015) and argued that: (1) Subspecies listed under the Act should have one major character that is distinct or diagnostic; (2) the choice of loci and statistical methods used by Zink *et al.* (2013) to analyze nuclear DNA were correct; and (3) interpretations of the niche analysis in Zink *et al.* (2013) are correct, and the California gnatcatcher overall has a wide ecological tolerance. Zink *et al.* (2016) concluded that no evidence for genetic structure exists among California gnatcatchers, and thus that the coastal California gnatcatcher is not a valid subspecies. Because the in-press article was received after the science panel met in August 2015, the information presented in this paper was not available for review by panelists. However, the Service reviewed Zink *et al.* (2016) and took into consideration its interpretation of the best available data in weighing all the evidence, including the data and analyses provided by the panelists, in making a final determination. Additional information regarding our analysis of Zink *et al.* (2016) is provided in the *Listable Entity Determination* section below.

Listable Entity Determination

The petition asserts that the coastal California gnatcatcher should be delisted. Working within the framework of the regulations for making delisting determinations, as discussed above, the petition asserts that the original data we used in our recognition of the coastal California gnatcatcher as a subspecies, and thus a listable entity under the Act, were in error. In determining whether to recognize the coastal California gnatcatcher as a valid (distinguishable) subspecies, we must base our decision on the best available scientific and commercial data. Additionally, we must provide transparency in application of the Act's definition of species through careful review and analyses of all the relevant data. Under section 3 of the Act and our implementing regulations at 50 CFR 424.02, a "species" includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. As such, a "species" under the Act may include any taxonomically defined species of fish, wildlife, or plant; any taxonomically defined subspecies of fish, wildlife, or plant; or any distinct population segment of any vertebrate species as determined by us per our Policy Regarding the Recognition of District Vertebrate Population Segments (61 FR 4721; February 7, 1996).

Our implementing regulations provide further guidance on determining whether a particular taxon or population is a species or subspecies for the purposes of the Act: "the Secretary shall rely on standard taxonomic distinctions and the biological expertise of the Department and the scientific community concerning the relevant taxonomic group" (50 CFR 424.11). For each species, section 4(b)(1)(A) of the Act mandates that we use the best scientific and commercial data available for each individual species under consideration. Given the wide range of taxa and the multitude of situations and types of data that apply to species under review, the application of a single set of criteria that would be applicable to all taxa is not practical or useful. In addition, because of the wide variation in kinds of available data for a given circumstance, we do not assign a priority or weight to any particular type of data, but must consider it in the context of all the available data for a given species.

For purposes of being able to determine what is a listable entity under the Act, we must necessarily follow a more operational approach and evaluate and consider all available types of data, which may or may not include genetic information, to determine whether a taxon is a distinguishable species or subspecies. As a matter of practice, and in accordance with our regulations, in deciding which alternative taxonomic interpretations to recognize, the Service will rely on the professional judgment available within the Service and the scientific community to evaluate the most recent taxonomic studies and other relevant information available for the subject species. Therefore, we continue to make listing decisions based solely on the basis of the best scientific and commercial data available for each species under consideration on a case-specific basis.

In making our determination whether we recognize the coastal California gnatcatcher as a distinguishable subspecies, and thus, whether the petitioned action is warranted, we will consider all available data that may inform the taxonomy of the coastal California gnatcatcher, such as ecology, morphology, genetics, and behavior. In particular, in this review, we focus on evaluating all new submitted and available data and analyses, including but not limited to the 2014 petition, the studies by Zink *et al.* (2000; 2013; 2016), McCormack and Maley (2015), and the science panel report (Amec 2015, entire) in the context of all the available data.

We do not address the petition's critiques or its citations to analyses and alternative interpretations of Atwood's morphological data (Thornton and Schiff 2014, pp. 14–21). In our 2011 90-day finding (76 FR 66255; October 26, 2011), we noted that on March 27, 1995, the Service published in the **Federal Register** (60 FR 15693) an extensive review of the Atwood data (including independent scientific analyses of the Atwood data) received during the public comment periods concerning the subspecies classification of the coastal California gnatcatcher. In that 1995 **Federal Register** document, we affirmed our earlier determination that the coastal California gnatcatcher is a valid subspecies (58 FR 16742, March 30, 1993; 58 FR 65088, December 10, 1993) and affirmed the coastal California gnatcatcher's threatened status under the Act. Thus, all of these critiques, analyses, and interpretations regarding Atwood's findings were previously considered by the Service in the 1995 listing determination and the 2011 petition decision. The 2014 petition provided no new information or analysis related to the morphological study of the coastal California gnatcatcher.

In our 2011 90-day finding (76 FR 66255; October 26, 2011), we provided a summary of our use of Atwood's morphological data as a part of a large suite of previous studies. We continue to consider those data to be part of the best scientific and commercial data available regarding taxonomy of the coastal California gnatcatcher. Furthermore, on September 15, 1995, the U.S. District Court for the District of Columbia dismissed with prejudice the lawsuit by the Building Industry Association of Southern California and other plaintiffs that sought to overturn the listing of the coastal California gnatcatcher. As part of that lawsuit, the court ordered the Service to release to the public the underlying data that formed the basis for Dr. Atwood's taxonomic conclusions. Given the court's 1995 ruling upholding the Service's recognition of the coastal California gnatcatcher as a valid subspecies, and the fact that no new data were presented by petitioners regarding morphological characteristics of California gnatcatchers, we do not further examine the petition's arguments about morphological data in this 12-month finding.

We also do not discuss the petition's assertions that because the Service has relied on mtDNA evidence in evaluating other species or subspecies for listing under the Act (Thornton and Schiff 2014, Exhibit D), we may not discount such information here. As discussed above, we base each listing decision on the best scientific and commercial data available for the individual species under consideration. Those data may or may not include results of genetic evaluations, including mtDNA analyses. Any data from genetic studies must be considered in the context of the suite of other relevant data available for a particular species. We previously considered the mtDNA data referenced in the petition along with other available information in our 2011 petition finding and concluded that the best available scientific and commercial information supports recognition of the coastal California gnatcatcher as a distinguishable subspecies.

As such, in this determination, we focus on the following topics: (1) Defining subspecies criteria for the coastal California gnatcatcher; (2) interpretations of the results of analyses from genetic studies used in the petition; and (3) interpretations of the results of an ecological niche model used in the petition.

Defining Subspecies Criteria for the Coastal California Gnatcatcher

In determining whether to recognize the coastal California gnatcatcher as a distinguishable subspecies, we must first define the criteria used to make this decision given the available information. The petition notes that subspecies divisions are often arbitrary or subjective (Thornton and Schiff 2014, pp. 21–22). Indeed, within the ornithological and taxonomic literature, there are no universally agreed-upon criteria for delineating, defining, or diagnosing subspecies boundaries. Historically, multiple researchers (for example, Mayr (1943); Rand (1948); Amadon (1949)) proposed that at least 75 percent of the individuals of a subspecies should be separable from other populations by a particular characteristic. The American Ornithologists' Union (AOU) Committee on Classification and Nomenclature of North and Middle American Birds (formerly known as the Check-list Committee), the widely recognized scientific body responsible for standardizing avian taxonomy in North America (Haig *et al.* 2006, p. 1587), gives their standard definition of subspecies with guidance on interpreting criteria (AOU 2015, entire):

> Subspecies should represent geographically discrete breeding populations that are diagnosable from other populations on the basis of plumage and/or measurements, but are not yet reproductively isolated. Varying levels of diagnosability have been proposed for subspecies, typically ranging from at least 75 to 95 percent. Because subspecies represent relatively young points along an evolutionary time scale, genetic differentiation between subspecies may not necessarily parallel phenotypic divergence. Thus, subspecies that are phenotypically but not genetically distinct still warrant recognition if individuals can be assigned to a subspecies with a high degree of certainty.

In the scientific literature, multiple authors have provided definitions with a wide-ranging variety of criteria for defining or refining the taxonomic rank of subspecies for avian taxa (for example, McKitrick and Zink (1988); Amadon and Short (1992); Strickberger (2000); Helbig *et al.* (2002); Patten and Unitt (2002); Avise (2004); Zink (2004); Futuyma (2005); Cicero and Johnson (2006); Haig *et al.* (2006); Phillimore and Owens (2006); Rising (2007); Skalski *et al.* (2008); Fitzpatrick (2010); Haig and D'Elia (2010); Patten (2010); Remsen (2010); and Patten (2015)); however, there is no consensus in the literature for defining subspecies criteria for avian taxa (Sangster 2014, p. 212).

The science panelists who were convened to evaluate the taxonomy and systematics of the coastal California gnatcatcher provided their individual recommendations for criteria used to define subspecies as described in the scientific literature. Most of the panelists highlighted the AOU subspecies criteria as the standard for avian taxa (Amec 2015, Panelist 1, p. 101; Panelist 3, p. 111; Panelist 4, pp. 116–117; Panelist 5, p. 124; Panelist 6, p. 135). Panelist 2 provided the definition of subspecies from Haig *et al.* (2011), which states that, "subspecies is generally defined as a breeding population that has measurably distinguishable genotypes or phenotypes (or both) and occupies a distinct geographic area within its species range (Avise 2004, Patten 2010, Remsen 2010)." However, all panelists affirmed that multi-evidence criteria should be used for distinguishing the coastal California gnatcatcher as a subspecies.

The petition bases its argument for delisting on the genetic analyses presented in Zink *et al.* (2000) and Zink *et al.* (2013) and the results of the ecological niche model discussed in Zink *et al.* (2013). The conclusions drawn from these analyses are based on the authors' overall frame of reference that the "gnatcatcher populations and subspecies are not monophyletic" at either the geographic or taxonomic level of organization (Zink *et al.* 2016, p. 65), and that no monophyletic units are found within the gnatcatcher consistent with any "hierarchical Linnaean taxon" or any other unit based on the "traditional 75 percent rule" to define subspecies (Zink *et al.* 2016, p. 65). In other words, the petition relies on a cladistic classification approach, generally used for describing species rather than subspecies, and which is based entirely on monophyletic taxonomic groups (Mallet 2007, p. 1). This phylogenetic species concept also invokes the concept of reciprocal monophyly (exclusive coalescence), in which all individuals in a given group have a common ancestor not shared by any other group, and all individuals in that group should be genetically distinct and distinguishable from members of other populations.

However, the science panelists explicitly rejected the use of reciprocal monophyly for defining subspecies status for the coastal California gnatcatcher (Amec 2015, p. 105). Reciprocal monophyly is rarely used by avian taxonomists, even in defining taxa at the species level, and this approach is not shared by the majority of scientists (Amec 2015, pp. 126, 104; Sangster 2014, p. 208). Many scientists consider subspecies to be incipient species that are not yet fully reproductively isolated (Amec 2015, p. 126), and the subspecies of the California gnatcatcher have likely not been separated for sufficient time to display characteristics of reciprocal monophyly (Amec 2015, p. 106). Additionally, because there are a number of gene lineages contained within any population, if a population becomes geographically (or genetically) divided into two distinguishable entities, a significant amount of time is required before each of the branches will become "fixed for different, reciprocally monophyletic gene lineages at any single gene" (Mallet 2007, p. 7).

In evaluating the best available information regarding the taxonomic and systematic status of the coastal California gnatcatcher, we disagree with the petition's argument, and conclude that a multi-evidence criteria approach is most appropriate for distinguishing subspecies. In accordance with the science panelists and conclusions in the scientific literature (Sangster 2014; McCormack and Maley 2015), we do not accept that reciprocal monophyly is an appropriate criterion for distinguishing subspecies of avian taxa in the case of the coastal California gnatcatcher.

We next examine the available data regarding factors appropriate for evaluating the subspecific status for the coastal California gnatcatcher. As described above, we reviewed and summarized the available morphological data in detail in previous Federal actions, including the 2011 90-day finding (76 FR 66255; October 26, 2011). No new information regarding the morphological characteristics of California gnatcatchers was submitted in the petition or in response to our request for information in our 2014 90-day finding (79 FR 78775; December 31, 2014). Because there was no new morphological information or analyses to review, the panelists considered the previous peer reviews and summaries of morphological data to represent the best available information and relied on this information in their evaluations (Amec 2015, p. 4). In the following sections, we, therefore, focus our discussion on the genetic and ecological information presented in the petition to delist the coastal California gnatcatcher.

We note that our evaluation applies specifically to the coastal California gnatcatcher and not to avian subspecies in general. Each possible subspecies has been subject to unique evolutionary forces, different methods of selection will act on each subspecies (genetic drift versus allopatric speciation), and the potential divergence time (recent versus more distant) will, therefore, lead to different signals, particularly genetically; as such, the methods for detecting each will be different (Amec 2015, pp. 101–102).

Analyses of Genetic Data Presented in the Petition

The petition relies on the results of a nuclear DNA analysis presented by Zink *et al.* (2013) as evidence that delisting the coastal California gnatcatcher is warranted based on taxonomic error. As described above, this analysis examined eight nuclear loci and concluded that no genetic structure was apparent within California gnatcatchers. In other words, any differences in California gnatcatchers represent a geographic cline, and thus all differences occur gradually along a north-south gradient and do not represent sharp distinctions between unique groups. The petition states that Zink *et al.* (2013) provided the data and analysis requested by the Service in our 2011 90-day finding (76 FR 66255; October 26, 2011) (Thornton and Schiff 2014, p. 30) and the best available information supporting the assertion that the coastal California gnatcatcher is not a valid subspecies. It is true that we recognized in the 2011 petition finding that results from nuclear DNA analyses are likely to better detect genetic evidence of population differentiation than mtDNA data (76 FR 66258; October 26, 2011). However, we did not suggest that the results of nuclear DNA studies would or should be considered determinative of the coastal California gnatcatcher's taxonomic status. Rather, we stated that future consideration of the status of the taxon "should wait for analyses of a variety of morphological, genetic (including nuclear and mtDNA) and behavioral evidence" (76 FR 66258; October 26, 2011). Consistent with our 2011 petition finding, we consider multi-evidence criteria involving multiple lines of genetic, morphological, and ecological scientific data to provide the best approach to determining the taxonomic status of the coastal California gnatcatcher.

With regard to the genetic evidence relied on in the current petition, multiple commenters from the scientific community and members of the science panel expressed concern regarding the nuclear DNA analysis and conclusions of Zink *et al.* (2013). Several panelists stated that Zink *et al.* (2013) chose markers with slow mutation rates that are inappropriate to evaluate the status of the coastal California gnatcatcher, given that their lineage diverged recently, likely within the last 12,000 years (for example, Panelist 6; Amec 2015, p. 147). For example, one science panelist stated that the loci chosen by Zink *et al.* (2013) do not in fact meet the standards recommended by the Service and the 2004 science panel, as described in the 2011 petition finding (76 FR 66255; October 26, 2011), given that loci with high mutation rates were requested (Amec 2015, p. 126).

We received information from the panelists and others from the scientific community (in response to our 90-day finding (79 FR 78775; December 31, 2014)) regarding the statistical methods presented in Zink *et al.* (2013). For example, Panelist 4 stated that the statistical analysis chosen for the nuclear loci genetic analysis (STRUCTURE) might be inappropriate because this method is not a statistically powerful approach for identifying genetic distinctions when divergence (genetic separation between two new groups) is modest, particularly given the small sample sizes used by Zink *et al.* (2013) (Amec 2015, p. 118).

We also received information regarding the approach and analysis of the nuclear markers used by Zink *et al.* (2013). Several commenters and members of the science panel found that McCormack and Maley's (2015) reanalysis of the data was more appropriate for considering subspecies than the original analysis by Zink *et al.* (2013). Additionally, several panelists found that the McCormack and Maley

(2015) analysis did support an observed population structure in California gnatcatchers (Amec 2015, Panelist 2, p. 108; Panelist 4, p. 118; Panelist 5, p. 126). However, one panelist (Amec, pp. 145–146) criticized both Zink *et al.* (2013) and McCormack and Maley (2015) for having too small of a sample size to reach any conclusions from analysis of nuclear data. We acknowledge that the sample sizes for the studies are small; however, as previously discussed, we must rely upon the best available scientific and commercial data for making our conclusions; as such, we take both interpretations of the study into consideration in our analysis.

As previously noted, Zink *et al.* (2016) presented a rebuttal to many of the critiques raised by McCormack and Maley (2015); however, this article was not available when the science panel workshop was convened. Our review of the information presented indicates that Zink *et al.* (2016) do not provide substantial defense to the claims that the markers they selected were inappropriate for analyzing population structure of the coastal California gnatcatcher. Zink *et al.* (2016) state that these loci and the mtDNA used in Zink *et al.* (2000) have detected evolutionarily distinct lineages in other species along the same distribution of the coastal California gnatcatcher, such as the Le Conte's thrasher (*Toxostoma lecontei*), the curve-billed thrasher (*T. curvirostre*), and the canyon towhee (*Melozone fusca*). However, their comparison is not supported by documentation of any potential genetic, morphological, or ecological similarities between the coastal California gnatcatcher and these species that would provide a strong basis for their conclusion that unrelated species with different life histories and evolutionary histories might necessarily experience similar rates and patterns of genetic divergence.

Zink *et al.* (2016) also contend that the reanalysis of the data presented in McCormack and Maley (2015) is invalid because the data do not represent the original subspecies boundary as defined by Atwood (1988) at 28° N. (Zink *et al.* (2016, p. 63) also perform a statistical analysis finding no structure in the population regardless of how it is divided). Still, we note that the range of the coastal California gnatcatcher subspecies as defined by the original listing in 1993 (58 FR 16742; March 30, 1993) is at 30° N., and several reanalyses of the morphological data (Atwood 1991, entire; Banks and Gardner 1992, entire; Link and Pendleton 1994, entire) have supported the southern limit of the range of the subspecies to be at approximately 30° N.

We reaffirm that the best available information indicates that the 30° N. is still the appropriate line to delineate the approximate southern limit of the subspecies' range, and, therefore, the genetic analyses based on that boundary are appropriate for considering the subspecific status. In support of this assessment, one science panel member also questioned the division of subspecies boundaries by Zink *et al.* (2013), stating that the presence of rare alleles north of the 30° N. boundary provides additional supporting scientific information that the coastal California gnatcatcher subspecies is valid. This panelist further noted that the choice by Zink *et al.* (2013) to use the 28° N. boundary does not answer the question as to whether genetic structure would have been detected if the accepted 30° N. latitudinal break was chosen (Amec 2015, p. 127). Zink *et al.* (2016, p. 61) dismiss the significant genetic structure observed in two loci in the reanalysis of McCormack and Maley (2015), stating that their statistical result "was driven by an excess of rare alleles as a result of larger sample sizes in the north . . . as well as by population expansion" (citing Zink *et al.* 2013). However, this assessment does not address the implication of rare alleles in the north, which, as noted by the science panelists and McCormack and Maley (2015), provides evidence of population structure. In fact, one panel member noted that the observation of rare alleles found in McCormack and Maley (2015) was especially significant given that the smaller population size in the north has been attributed to the presence of reported population declines or bottlenecks, which often remove rare alleles (Allendorf *et al.* 2013, p. 109) (Amec 2015, p. 127).

An additional difference in the views regarding the genetic analysis presented in Zink *et al.* (2013) relates to how scientists interpret negative results. The petition argues that a lack of structure detected means that such genetic or population structure is overall lacking. However, negative results (such as failure to detect structure) can be interpreted as either the true absence of genetic structure or as simply inconclusive. Several panelists stated that they found the results of Zink *et al.* (2013) to be inconclusive overall. In addition, one panel member noted that the methods used in Zink *et al.* (2013) might lack adequate statistical power to detect population structure, given that relatively few loci were used (Amec 2015, p. 125). This highlights the significance of the detection of structure by McCormack and Maley (2015, pp. 382–383), despite the small number of markers used.

We also received information from the science community and from the panelists regarding the use of only a small number of neutral genetic markers by Zink *et al.* (2013). Two panelists stated that the observed morphological difference between the northern and southern populations of California gnatcatchers is likely only caused by a very small portion of the genome (Santure *et al.* 2013, p. 3959; Poelstra *et al.* 2014, p. 1414; Amec 2015, pp. 113, 117). Thus, the chance of detecting that difference using few neutral genetic markers is very small. The apparent absence of species-wide genetic structure at a handful of neutral markers unconnected to phenotype does not necessarily indicate the absence of important adaptive differences among specific groups (Amec 2015, p. 118).

The petition contends that use of DNA data can result in more clear and decisive answers regarding subspecies limits than morphological characteristics (Thornton and Schiff 2014, p. 21). We concur with the petition's assertions and the panelists' summaries that genetic data can in some cases provide clear diagnostic information regarding the geographic limits of related populations, which can then be interpreted and applied in assessing taxonomic treatments. However, we also concur with the panelists that evaluation of genetic data must be thorough, analyzed using genetic markers appropriate for the time scale of likely divergence, and analyzed using appropriate statistical methods. We agree with the panelists that the number and type of genes tested by Zink *et al.* (2013) were insufficient, and that the analysis relied upon in the petition was too limited to "prove the negative"; that is, we do not agree with the assertion in the petition that the coastal California gnatcatcher subspecies is not valid based on analysis of DNA data and the original listing was in error. Rather, we conclude that the best available genetic information, including independent evaluations from the science panelists and reanalyses of data from members of the scientific community (for example, Andersen 2015, pers. comm.; McCormack and Maley 2015), indicates that there is some genetic evidence for population structure in the California gnatcatcher and that this evidence provides some support for the distinguishability of the coastal California gnatcatcher as a subspecies. As discussed above, we consider multi-evidence criteria involving multiple lines of genetic, morphological, and ecological scientific data to provide the best approach to determining the taxonomic status of the coastal California gnatcatcher.

One recommendation made by five of the six science panelists was that existing or any newly collected samples be reanalyzed using large numbers of genomic data (AMEC 2015, pp. 102, 109, 121–122, 131, 141), particularly, thousands to tens of thousands of single nucleotide polymorphisms (SNPs) that represent a large portion of the genome. On July 6, 2016, Zink sent to the Service an accepted abstract to be presented at the 2016 North American Ornithology Conference in August (Zink 2016b, pers. comm.). The abstract references a study in which Váquez-Miranda and Zink examine thousands of SNPs for the coastal California gnatcatcher and other Baja California bird species. The authors state that the study results show a lack of population structure in the coastal California gnatcatcher (Zink 2016b, pers. comm.).

The science panelists who recommended the use of SNPs included several provisos. They cautioned that the SNP dataset be analyzed using samples from individuals across the range of the California gnatcatcher species, appropriate hypothesis testing be used, appropriate statistical methods be used (for example, testing for outlier loci (Funk *et al.* 2012, p. 493)), and the data be released publicly to allow for transparency of analysis (AMEC 2015, pp. 104, 121, 131, 141, 151). If incorrect methodology is used, the SNP analysis will unlikely be able to identify adaptive divergent groups, particularly given that the vast majority of SNPs in any dataset will be neutral (Amec *et al.* 2015, p. 131; Funk *et al.* 2012, p. 492–494). As stated previously, given the recent genetic separation (divergence) of the coastal California gnatcatcher, adaptive divergence of its genomic structure (that is, those few key genes responding to local selection pressures) is likely represented in only a few SNP loci, which can be difficult to locate even within a large set of SNPs (Amec 2015, p. 121).

The underlying study identified by Zink (2016b, pers. comm.) has not been provided to us and has not been peer-reviewed or published. The abstract submitted by Zink (2016b, pers. comm.) did not include information regarding the sampling methods used in the study or the statistical methods used to analyze the samples. The division between subspecies of California gnatcatchers used by Váquez-Miranda and Zink appears to be located farther south than the recognized boundary for the subspecies at 30° N., which may confound the results (Zink 2016b, pers. comm.). In sum, the submitted abstract does not provide sufficient detail and information to enable us to adequately evaluate its conclusions. Therefore, we do not consider the abstract to provide the best available information regarding the subspecific status of the gnatcatcher. We will consider the underlying study and data, along with all new information provided on the coastal California gnatcatcher, as we receive it.

Ecological Niche Model

The petition also relied on the results of an ecological niche model constructed by Zink *et al.* (2013). In general, an ecological niche model represents an estimation of the different niches (for example, existing, potential, occupied) and uses estimates of suitable conditions from observations of species' presence (Peterson *et al.* 2011, p. 271). The model is then constructed (usually with a specialized computer program) by overlaying that occurrence data with environmental data such as temperature, precipitation, elevation, vegetation type, or other habitat characteristics. The model then can be used for a variety of functions; for example, it can be used to predict an entity's occurrence elsewhere on the landscape or compare two populations or subspecies to determine similarities of occurrence, as was the case for Zink *et al.* (2013). The model constructed by Zink *et al.* (2013) compared temperature and precipitation data for habitats throughout the range of the California gnatcatcher species as a whole. The petition asserts, based on the results of the ecological niche model that, although California gnatcatchers in the northern portion of their range inhabit a distinctive coastal scrub habitat, no background environmental differences or climactic differences are present (Thornton and Schiff 2014, p. 30). Zink *et al.* (2013, p. 456) also stated that the results of their niche model indicate that California gnatcatchers overall exhibit broad ecological tolerance. The petition asserted that the lack of differentiation in the modeled niches is indicative of no evidence for subspecies divisions based on the variables included in the model.

In response to our request for information in our 90-day finding (79 FR 78775; December 31, 2014), we received differing interpretations of the ecological niche model from Zink *et al.* (2013). For example, McCormack and Maley (2015, p. 384) disagreed with the interpretation of the niche model results stating that the model results provided evidence of strong differentiation between the ecological niches of different populations of California gnatcatchers and that Zink *et al.* (2013) had improperly failed to reject their null hypothesis that the niches and background areas were equally divergent. We also received information from one member of the public who indicated that he was provided the opportunity to comment on a draft version of the Zink *et al.* (2013) paper and had identified "fundamental flaws" with the ecological niche model analysis that were not addressed in the final publication (Atwood 2015, pers. comm.).

The science panelists also disagreed with the interpretation of the results of the ecological niche model presented in Zink *et al.* (2013). One panelist cited the lack of clarity as to how the model results were interpreted, and the panelist concluded that the model results do show differences in the environments inhabited by the coastal California gnatcatcher and the other subspecies farther south, in support of the conclusions of McCormack and Maley (2015) (Amec 2015, p. 113).

The ecological niche model presented by Zink *et al.* (2013) was constructed using broad-scale bioclimatic variables. Two panelists stated that habitat variables such as vegetation type, structure, or composition should have been used for constructing the niche model since these variables incorporate a better ecological approach for distinguishing subspecies (Amec 2015, pp. 119, 148). In addition, our assessment of available vegetation maps from Mexico and documentation provided in the literature (for example, Rebman and Roberts 2012, p. 25) indicate that there is a clear distinction between plant communities in Baja California at about the 30° N. latitude and, therefore, separate ecological niches; two panelists also emphasized the distinction between habitat types (Amec 2015, pp. 104, 129).

Further support for the interpretation of McCormack and Maley (2015) is provided in a new paper by Theimer *et al.* (2016). In that study, the researchers examined an ecological niche model performed by Zink (2015, pp. 79–82) for the southwestern willow flycatcher (*Empidonax traillii extimus*). From that model, Zink (2015, pp. 83–84) concluded that the southwestern willow flycatcher showed no ecological distinctiveness from other willow flycatchers. However, Theimer *et al.* (2016, pp. 292–293) reconstructed the Zink (2015) ecological niche model comparing the southwestern willow flycatcher and an unrelated species, the yellow warbler (*Setophaga petechia*), and found no ecological distinctiveness between the two species. In other words, the model was unable to predict any difference in niche (specific habitat) use between the two unrelated species. Theimer *et al.* (2016) state that the reason for this is the use of overly broad environmental data that may fail to detect ecological distinction on a finer scale, such as that which might be expected for subspecies or closely related species that would be expected to have some ecological characteristics in common. Theimer *et al.* (2016, p. 294) argued that ecological niche models needed to include other habitat characteristics beyond broad measures of temperature and precipitation that were used for both the southwestern willow flycatcher and the coastal California gnatcatcher (Zink *et al.* 2013; Zink 2015). The authors further concurred with McCormack and Maley (2015) that Zink *et al.* (2013) had improperly failed to reject the null hypothesis for their niche model (Theimer *et al.* 2016, p. 294).

In the Zink *et al.* (2016) article, published in response to the critique of Zink *et al.* (2013) by McCormack and Maley (2015), Zink *et al.* (2016, p. 63) defended their interpretation of the California gnatcatcher ecological niche model, stating that most widespread species occupy different climactic niches. They stated that the fact that one portion of the California gnatcatcher species population occupies mesic versus xeric habitat does not necessarily indicate that there are evolved niche differences (Zink *et al.* 2016, p. 63). Following the publication of the article by Theimer *et al.* (2016), which, as discussed above, presented a differing analysis and interpretation of the niche modeling results presented in Zink (2015) for the southwestern willow flycatcher, Zink submitted a draft copy of a scientific article to the Service on July 1, 2016, responding specifically to Theimer *et al.* (2016)'s critique (Zink 2016a, pers. comm.). In the draft article, Zink argues that the reanalysis by Theimer *et al.* (2016) only found weak partitioning between niches and that the Zink (2015) study used standard methodology for ecological niche models. However, the draft article does not address the larger concern raised by Theimer *et al.* (2016) that the environmental data used for the analyses presented in Zink (2015) for the southwestern willow flycatcher as well as our similar concern for the niche model results presented in Zink *et al.* (2013) for the coastal California gnatcatcher were too coarse to reliably detect differences in ecological niches. The best available information indicates that there is a difference in habitat used by the populations of the California gnatcatchers north of 30° N. latitude and the populations farther south, and this habitat difference is consistent with both observed morphological differences and the slight genetic variation (as described in *Analyses of Genetic Data Presented in the Petition* above) that occurs at the 30° N. latitude that has defined the southern limit of the range of the coastal California gnatcatcher since the time of listing. Therefore, we conclude that ecological differences help distinguish the coastal California gnatcatcher as a subspecies.

Summary

After careful review of the best available information including information presented in the petition, information submitted by the public, information provided by the science panelists, and all other available information, we find that the results of the genetic analyses and niche modeling presented in Zink *et al.* (2000; 2013; 2016) do not provide sufficient information to support the petition's assertion that the coastal California gnatcatcher is not a valid subspecies and was listed in error. While the analyses presented by Zink *et al.* (2013) provide additional information related to the genetic characteristics of the California gnatcatcher, there are significant concerns with the methods used and the interpretations of the results. We reject the petition's argument that subspecies listed under the Act should have one major character that is distinct or diagnostic. We concur with the input from the assessments provided by the science panelists and the information submitted by the scientific community and the public in response to our request for information, and our determination is based on all available data that may inform the taxonomy of the coastal California gnatcatcher. Multi-evidence criteria involving multiple lines of genetic, morphological, and ecological scientific data support our recognition of the coastal California gnatcatcher as a distinguishable subspecies. Therefore, we conclude that the best scientific and commercial information available indicate that the coastal California gnatcatcher is a distinguishable subspecies, and we continue to recognize it as a listable entity under the Act (that it is a "species" as defined in section 3 of the Act and is thus eligible to be listed as a threatened species or endangered species).

Having reviewed the best available information regarding the taxonomy of the coastal California gnatcatcher and determined it is a distinguishable subspecies, we next evaluate information regarding its appropriate status under the Act.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In making this finding, information pertaining to the coastal California gnatcatcher in relation to these five factors is discussed below. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat. We then attempt to determine if that factor rises to the level of a threat, meaning that it may drive or contribute to the risk of extinction of the species such that the species warrants listing as an endangered species or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of an endangered species or threatened species under the Act.

In 2010, we conducted a threats analysis in our 5-year review for the coastal California gnatcatcher (Service 2010, entire). The following analysis of factors affecting the species is a summary and update of the information presented in the 2010 analysis, which is incorporated by reference in this section. We updated the summary presented here, where appropriate, with new information from the literature or received from the public in response to our request for information in the 90-day finding (79 FR 78775; December 31, 2014). As described above in Background, the petitioners did not provide information on any of the factors. However, several respondents to our request did submit information regarding factors affecting the species. Our 2010 5-year review is available online at *http://www.regulations.gov* in Docket Number FWS–R8–ES–2014–0058 as a Supporting Document (ID: FWS–R8–ES–2011–0066–0003) and at our Environmental Conservation Online System Web page *http://ecos.fws.gov/tess_public/profile/speciesProfile?spcode=B08X* or by request from the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

The following sections include summary evaluations of nine potential threats to the coastal California gnatcatcher that we identified in the 2010 5-year review as having impacts on the subspecies or its habitat throughout its range in the United States and Mexico. Potential threats that may impact the subspecies are those actions that may affect individuals or habitat either currently or in the future, including habitat loss from urban and agricultural development (*Factor A*), grazing (*Factor A*), wildland fire (*Factor A* and *Factor E*), vegetation type conversion (*Factor A*), climate change (*Factor A* and *Factor E*), disease (*Factor C*), predation (*Factor C*), fragmentation (*Factor A* and *Factor E*), and brood parasitism (*Factor E*). We also evaluate the extent to which existing regulatory mechanisms (*Factor D*) may ameliorate threats associated with the other factors. We further note that potential impacts associated with overutilization (*Factor B*) were evaluated in the 2010 5-year review, but we concluded that this factor had low or no impacts, overall, across the subspecies' range (see Service 2010, p. 21). We did not receive any information that impacts associated with overutilization have changed since that time. Based on the best available scientific and commercial data, we have not identified any new threats to the coastal California gnatcatcher since the 2010 5-year review.

To provide a temporal component to our evaluation of threats, we first determined whether we had data available that would allow us to reasonably predict the likely future impact of each specific threat over time. Overall, we found that, for many threats, the likelihood and severity of future impacts became too uncertain to address beyond a 50-year timeframe. For example:

- The Natural Community Conservation Planning (NCCP) Act, in conjunction with the Service's Habitat Conservation Planning (HCP) process established under section 10(a)(1)(B) of the Act has established long-term NCCP/HCPs within the U.S. range of the coastal California gnatcatcher. These plans address development impacts on the subspecies and its habitat for 50 to 75 years into the future, depending on the plan terms and conditions. We, therefore, consider 50 years a reasonable timeframe for considering future impacts.
- Laws governing urban development under State environmental laws, such as the California Environmental Quality Act and the NCCP Act, have remained largely unchanged since 1970 and 1991, respectively; thus, we consider existing regulatory mechanisms sufficiently stable to support a 25- to 50-year timeframe.
- In analyzing potential impacts from disease, predation, grazing, and brood parasitism, we considered all available information regarding any future changes that could alter the likelihood or extent of impacts. We had no such information extending beyond a 50-year timeframe.
- Although information exists regarding potential impacts from climate change beyond a 50-year timeframe, downscaled climate model projections for this region extend only to the 2060s.

Therefore, a timeframe of 50 years is used to provide the best balance of scope of impacts considered versus certainty of those impacts.

Urban and Agricultural Development

The largest impacts to coastal sage scrub in California, including within the range of the coastal California gnatcatcher, both past and present, have been due to the effects of urbanization and agriculture (Cleland *et al.* 2016, p. 439). Development for urban use involves clearing of existing vegetation. Urban development not only results in buildings, roads, and other infrastructure, which are permanent, but also includes "temporary" impacts, such as pipeline installation or heavy equipment activity adjacent to permanent urban development (Service 2010, p. 12). Without active habitat restoration actions, sites formerly supporting coastal sage scrub vegetation that have undergone severe disturbance (from heavy equipment and earth-moving activities) require decades to recover (Stylinski and Allen 1999, p. 550). At the time of listing, we reported that 58 to 61 percent of coastal sage scrub habitat had been lost in the three counties that supported about 99 percent of the coastal gnatcatcher population in the United States; we further identified urban and agricultural development as the primary cause for this loss of habitat (58 FR 16751; March 30, 1993).

Urban development has continued to occur throughout the range of the coastal California gnatcatcher, and in our 2010 5-year review we concluded that urban development was an ongoing threat to the subspecies (Service 2010, pp. 12–15; 21). For the purposes of this status review, we evaluated the current protection status of coastal sage scrub (the primary habitat type that supports the coastal California gnatcatcher) within the U.S. range of the subspecies using geospatial data from the U.S. Geological Survey. We note, however, that the distribution of the coastal California gnatcatcher within the United States is not necessarily the same as the distribution of coastal sage scrub vegetation, because not all coastal sage scrub is occupied by coastal California gnatcatchers at any given time (Winchell and Doherty 2014, entire). Our analysis for the U.S. portion of the range found that 16 percent of coastal sage scrub receives permanent protection and minimal human use; 35 percent is permanently protected from urban development but allows multiple uses including off-highway vehicle use or mining; and 49 percent has no assured protections preventing urban development (Service 2016a).

Currently, much of the subspecies' range in the United States, which includes coastal sage scrub as well as other habitat types and some partly developed areas, is included in completed NCCP/HCP plans where the coastal California gnatcatcher is a "covered species." Other NCCP/HCPs within the subspecies' range in the United States are in various stages of development, such as the North County Multiple Species Conservation Plan in north-central San Diego County, the Orange County Transportation Authority M2 NCCP/HCP, and the Rancho Palos Verdes NCCP/HCP in Los Angeles County. Within the northernmost portion of the subspecies' range in Los Angeles and Ventura Counties, the draft Rancho Palos Verdes NCCP/HCP is the only plan in development. Though the above list represents plans that are not yet permitted or fully implemented, specific conservation measures are included in these plans that provide protections for the subspecies and its habitat. Implementation of existing HCPs and the ongoing development of additional NCCP/HCPs have significantly reduced the impacts of urban development to coastal California gnatcatcher habitat in the United States by directing urban development away from some areas of coastal scrub vegetation while establishing habitat reserves that provide conservation benefits to the subspecies and other species. These plans are making substantial contributions to the conservation of the subspecies by creating a network of managed preserves with linked core habitat areas.

As reported in our 2010 5-year review, we estimated that 59 percent of suitable (modeled) coastal sage scrub habitat would be conserved with full implementation of four currently permitted NCCP/HCPs and one HCP (Service 2010, p. 15). For that analysis, modeled habitat consisted of coastal scrub vegetation within the U.S. portion of the range of the coastal California gnatcatcher as defined by reported observations, elevation, and coastal scrub vegetation (using CDF (2002) vegetation data). Using updated vegetation data (CDF 2015), we prepared a new geospatial analysis of the previously modeled coastal scrub habitat within the subspecies' range and within the planning-area boundaries of these NCCP/HCPs (as compared to the 2010 analysis that estimated acres of habitat expected to be conserved with full implementation). Based on our 2016 analysis, our revised estimate found that these plans encompass approximately 55 percent of the coastal sage scrub habitat within the U.S. range of the coastal California gnatcatcher (Service 2016a). We also evaluated the amount of land currently within conservation reserves established under these plans and estimated that approximately 47 percent of the plans' conservation targets have been reached (Service 2016a). This means that 28 percent of habitat in the U.S. portion of the coastal California gnatcatcher's range is currently conserved by NCCP/HCP plans.

Outside of the United States, urban development continues and is expected to continue into the future (Harper *et al.* 2011, p. 26; Meyer *et al.* 2016, pp. 10 and 13). Conservation of vegetation within the California floristic province of Baja California, Mexico, is receiving increasing attention (Meyer *et al.* 2016, p. 14). Two privately managed reserves were recently established in Baja California north of 30° N. latitude: (1) Punta Mazo in 2012, which consists of a portion of the tidal estuary and sand dune plant community at San Quintín Bay; and (2) La Reserva Natural Valle Tranquilo, purchased in 2006 and expanded in 2013, a 20,000-ac (9,094-ha) reserve south of San Quintín (Riley 2016, pers. comm.), which is at the very southern edge of the California floristic province found in Baja California, at the transition from coastal sage scrub/chaparral to desert plant communities (Meyer *et al.* 2016, pp. 12–13). Two Federal parks are also found in mountainous areas in northwestern Baja California. However, collectively, these four conservation areas encompass very little suitable California gnatcatcher habitat. No equivalent regulatory mechanisms to the NCCP/HCP process exist in Mexico. In that portion of the subspecies' range, Federal, State, and local laws provide limited protections to coastal California gnatcatcher habitat (see the *Existing Regulatory Mechanisms* section below).

In order to estimate the distribution of coastal sage scrub in northern Baja California, we created a digital map of the coastal sage scrub vegetation defined by and illustrated in Rebman and Roberts (2012, p. 22). Based on the digitized version of this published map, we created a boundary of the area in northern Baja California that contains coastal sage scrub vegetation; this acreage totaled approximately 1,862,413 ac (753,691 ha). We then prepared a coarse estimation of extant coastal sage scrub vegetation from our delineation of Rebman and Roberts (2012, p. 22) by removing those areas that have been converted to urban and agricultural development, as estimated from composite aerial images from ESRI World Imagery (2013). We estimated approximately 1,704,406 ac (689,749 ha) of coastal sage scrub habitat in northern Baja California, from 30° N. to the United States-Mexico border (Service 2016a). This represents a difference of 158,007 ac (63,942 ha), or about 8.5 percent, from the map prepared by Rebman and Roberts (2012, p. 22) of their estimate of coastal sage scrub vegetation. Though this figure represents a rough estimate of coastal sage scrub vegetation in northern Baja California as of 2013, it is the only available analysis of change in amount of coastal sage scrub habitat available to us at this time.

In our 2010 5-year review, we indicated that the threats to the coastal California gnatcatcher as a result of agricultural development have been tempered in recent years by implementation of regulatory mechanisms, especially the State of California's NCCP process and the Federal HCP process (Service 2010, p. 14). We also indicated that the rate of loss of coastal California gnatcatcher habitat due to agricultural development has declined in its southern California range. More specifically, 1890–1930 was an intensive agricultural period in California with the expansion of dry land farming as well as rapid growth of intensively irrigated fruit and vegetable crops (Preston *et al.* 2012, p. 282). An unknown amount of coastal sage scrub within the U.S. range of the coastal California gnatcatcher was lost or modified during this time period.

The post-World War II population boom resulted in the conversion of many large agricultural areas to urban and suburban developments in southern California (Preston *et al.* p. 282). We used data from the Farmland Mapping and Monitoring Program (FMMP) of the Division of Land Resource Protection in the California Department of Conservation (CDC) to evaluate land use changes in California since 1984 (CDC 2016). Although not all areas of some counties have been inventoried, a review of these data for San Diego, Orange, Los Angeles, and Riverside Counties indicate net losses in prime farmland, from 1984 to 2012, of 8,508 ac (3,443 ha), 16,874 ac (6,829 ha), 12,326 ac (4,988 ha), and 82,611 ac (33,431 ha) (CDC 2016), respectively, for a total net loss of 120,319 ac (48,691 ha). Correspondingly, the reported net gains in urban and built-up land for the same time period and the same counties were 107,988 ac (43,701 ha), 59,264 ac (23,983 ha), 53,113 ac (21,494 ha), and 161,615 ac (65,403 ha) (CDC 2016), respectively, for a total net increase of 381,980 ac (154,582 ha). These numbers indicate that, although agricultural activities have declined in southern California, these former farmlands have likely transitioned to urbanized areas rather than been allowed to revert to or been restored as native habitats.

Because of the limited regulatory mechanisms in Mexico (see *Existing Regulatory Mechanisms* section below), agricultural activity continues to be a stressor within the subspecies' range in that country as a result of land clearing for both agriculture and grazing practices, particularly in northwestern Baja California (for example, Harper *et al.* 2011, pp. 28 and 31; Meyer *et al.* 2016, p. 10). These effects are likely to continue into the future.

In summary, urban development was identified as a threat at the time of listing and as an ongoing threat in our 2010 5-year review. Our 2016 evaluation of conserved lands established within the U.S. range of the subspecies indicates that approximately 55 percent of suitable coastal California gnatcatcher habitat is targeted for conservation by five regional NCCPs/HCPs, and that 47 percent of that goal has been achieved. Although the impact of urban development has been curtailed in NCCP/HCP planning areas and has decreased since the time of listing, conservation of the subspecies and its habitat within the plan areas is not expected until current conservation plans are more fully implemented and future conservation plans are approved and permitted in other portions of the subspecies' range. Suitable habitat that is not yet conserved may be subject to urban development or other stressors. Furthermore, although lands within conserved areas are not at risk of destruction or modification from development, other threats, as discussed below, remain. Additionally, some areas of suitable habitat would remain outside areas targeted for conservation and could be developed or impacted in the future. Therefore, urban development continues to result in the destruction, modification, or curtailment of the coastal California gnatcatcher's habitat, and represents a current, medium-level stressor to the coastal California gnatcatcher across its range in the United States and Mexico that has the potential to result in the loss of gnatcatchers at the population level and the loss of large but isolated patches of habitat. This stressor will continue to impact the subspecies and its habitat into the future.

The impacts to the subspecies related to agricultural development is low in the United States, but our recent evaluation of remaining coastal sage scrub habitat in Baja California indicates that agricultural development remains as a medium- to high-level stressor for the subspecies' range in Mexico; we anticipate these impacts will continue into the future.

Grazing

Effects of grazing and browsing from cattle, sheep, and goats include eating and trampling of coastal scrub plants. In the 2010 5-year review, we found that the effects of grazing can result in the loss and modification of coastal California gnatcatcher habitat and promote vegetation type conversion (the modification of one habitat type to another through the effects of one or more stressors working individually or in combination—ultimately resulting in the destruction of the original habitat type) (see the *Vegetation Type Conversion* section below); at that time, we concluded that grazing was a minor threat to the subspecies (Service 2010, pp. 18, 21). Data from the FMMP indicate that there have been substantial declines in grazing land in San Diego and Riverside Counties from 1984 to 2012. These declines range from approximately 19,500 to 34,000 acres (7,689 to 13,759 ha). A smaller decline was reported for Orange County (3,265 ac (1,321 ha)), and a small increase was reported for Los Angeles County (6,066 ac (2,455 ha)) (CDC 2016), though not all areas of these counties have been inventoried. Overall, grazing is considered a low-level stressor within the subspecies' range in the United States that has a temporary impact to only small amounts of habitats and individual gnatcatchers, due to the decline in grazing activity and increased regulation of grazing by local jurisdictions (for instance, city ordinances).

The effects of grazing practices to coastal California gnatcatcher habitat in Mexico are less concentrated as compared to the United States because livestock are seasonally moved. However, grazing in coastal scrub habitat in Mexico can still result in vegetation type conversion, and as noted above, land clearing for grazing purposes has been documented within northern Baja California (Meyer *et al.* 2016, p. 10). Therefore, grazing continues to pose a medium-level stressor that temporarily impacts large patches of habitat and gnatcatchers at the population level within the subspecies' range in Mexico.

Wildland Fire

Wildland fire can result in the direct loss of the coastal scrub plants that the coastal California gnatcatcher uses for foraging, breeding, and sheltering. In our 2010 5-year review, we found that wildland fire poses a threat to coastal California gnatcatcher habitat (Service 2010, pp. 15–18, 21). In that review, we noted that, absent other disturbances, coastal scrub vegetation can re-grow in some areas post-wildland fire in as little as approximately 3 to 5 years (Service 2010, p. 21). However, new information suggests that the process needed for coastal scrub vegetation to recover sufficiently to provide suitable habitat for the coastal California gnatcatcher is more complex. Winchell and Doherty (2014, p. 543) examined coastal California gnatcatcher recolonization rates after the wildland fires of 2003 in San Diego County; they found that coastal California gnatcatchers recolonize burned areas from the outside in, "[moving] in from the fire perimeter, rather than colonizing the center of the burned area immediately" (see also van Mantgem *et al.* 2015, p. 136). Moreover, the quality of the habitat where recolonization occurs is also important, with higher-quality unburned habitat supporting source populations for recolonization of burned areas and higher-quality burned habitat being more likely to be recolonized as the vegetation regrows (Winchell and Doherty 2014, p. 543). This study concluded that the coastal California gnatcatcher will recolonize burned areas, but that it can take more than 5 years post-burn for populations to reach pre-burn occupancy levels, even in higher-quality habitat areas (Winchell and Doherty 2014, p. 543).

Similarly, a 2012 study of coastal California gnatcatchers within the Central and Coastal Reserves in Orange County found that, following two large fires in 2007 (Windy Ridge and Santiago Fires) that burned approximately 75 percent of the Central Reserve, occupancy of surveyed plots in 2011 (4 years post-fire) was 10.1 percent (7 of 65 plots) in burned areas (Leatherman Bioconsulting Inc. 2012, pp. i, 5). The severity of these fires within the Central Reserve also affected occupancy, with no occupancy of coastal California gnatcatchers observed within severely burned plots, as compared to 23 percent occupancy for lightly burned plots (Leatherman Bioconsulting Inc. 2012, p. 5). The 2007 fires resulted in a large loss of coastal sage scrub habitat in the Central Reserve, and the study found that only 12.7 percent of plots were occupied by the subspecies as compared to 34.3 percent of occupied plots for the Coastal Reserve (Leatherman Bioconsulting Inc. 2012, p. 5). These findings are supported by an observation made by one land manager who submitted information to us in response to our request for information in our recent 90-day finding (79 FR 78775; December 31, 2014). This land manager indicated that it took 10 years of restoration activities after the 2003 San Diego wildland fires for coastal California gnatcatcher to return to previously occupied habitat in certain burned areas within San Diego County (Johanson 2015, pers. comm.). The U.S. Geological Survey, in partnership with the San Diego Management and Monitoring Program, is conducting additional research to better understand the effects of wildland fire on coastal California gnatcatcher occupancy within coastal scrub vegetation in southern California (Kus and Preston 2015, entire).

As discussed in our 2010 5-year review (Service 2010, pp. 15–18), the frequency of wildland fire has risen due to an increase in rates of ignition along the urban-wildland interface and controlled burning practices in Mexico. The greater number of fires, many of which have burned large areas of coastal scrub, has resulted in more areas of young growth coastal scrub vegetation that do not provide suitable coastal California gnatcatcher habitat. The 2010 5-year review noted that roughly 235,226 ac (95,193 ha) of modeled coastal California gnatcatcher habitat in the United States burned from 2003 to 2007 (Service 2010, pp. 15–17), which included several very large fires (see Service 2010, p. 16, Figure 3). As noted above (see *Urban and Agricultural Development* section), that analysis used modeled habitat consisting of coastal scrub vegetation within the U.S. portion of the range of the coastal California gnatcatcher. Using updated fire perimeter spatial data from the California Department of Fire and Forestry Protection (CDF) (CDF 2014) and our previously defined modeled coastal California gnatcatcher habitat, we estimated that 54,429 ac (22,027 ha) burned from 2008–2014, which also includes areas that may have burned during both the 2003–2007 and 2008–2014 time periods (Service 2016a). For southern California fires in 2015, we evaluated fire perimeter geospatial data and determined that the Calgrove Fire (439 ac (177.6 ha) total) in Los Angeles County burned approximately 167.5 ac (67.8 ha) of coastal California gnatcatcher habitat (Service 2016a). In total, from 2003 to 2015, approximately 289,822 ac (117,286 ha) or about 45 percent of modeled coastal California gnatcatcher habitat has burned.

Wildland fire, and how often it reoccurs in an area, is a major contributor to vegetation type conversion from coastal sage scrub to annual grassland, a vegetation type that does not support the breeding, feeding, or sheltering needs of the coastal California gnatcatcher. This is particularly problematic when frequency of wildland fires increases above the historic fire regime for coastal sage scrub, which increases the incidence of vegetation type conversion. In conjunction with several other stressors, wildland fires promote the growth of nonnative plant species, which can outcompete and displace native plant species. This occurrence results in the modification and, ultimately, the loss of coastal scrub habitat. Furthermore, the senescence of these annual nonnative annual plants creates higher fuel loads than are found in native coastal scrub habitat, accelerating the effects of the wildland fire-type conversion feedback loop (see *Vegetation Type Conversion* section below). Our spatial data show that a total of about 53,343 ac (21,587 ha) of modeled coastal California gnatcatcher habitat in the United States has burned at least twice since 2003, with some areas having burned three to four times (Service 2016a).

At the time of listing, wildland fire was identified as a substantial threat to the coastal California gnatcatcher and its habitat; it was further identified as an ongoing threat in the 2010 5-year review. Although currently established NCCP/HCPs provide for the establishment of coastal sage scrub reserves and include fire management as one of their primary objectives, there is no mechanism or conservation measure currently in place that can fully prevent the recurrence of natural or human-caused destructive wildland fires in coastal California gnatcatcher habitat. Therefore, wildland fire represents a medium-level stressor leading to the destruction, modification, or curtailment of habitat or range of the coastal California gnatcatcher that causes large-scale, temporary alterations to coastal sage scrub habitat and may result in the loss of some gnatcatcher pairs throughout the subspecies' range. According to the best available data, it will continue to impact the subspecies and its habitat into the future.

Vegetation Type Conversion

The presence of invasive, nonnative plant species, in combination with one or more stressors, such as severe physical disturbance (for example, clearing by heavy machinery), livestock activity, wildland fire, and anthropogenic atmospheric pollutants (particularly nitrogen compounds) can cause a shift from native plants towards a nonnative plant community and result in vegetation type conversion. In the 2010 5-year review, we found that vegetation type conversion of coastal sage scrub to nonnative grasses was an ongoing threat to the coastal California gnatcatcher, given that nonnative grasses do not support breeding for the subspecies (Service 2010, pp. 18–21). Depending on the influencing factors, this conversion can occur over various temporal and spatial scales. In particular, the nonnative annual plant–wildland fire feedback loop can result in the type conversion of large areas of habitat over a relatively short period of time (Service 2010, pp. 15–18). Information provided to us by two land managers within reserves in San Diego County indicates that active management to control nonnative vegetation is needed to maintain habitat quality due to re-occurring wildand fires (Center for Natural Lands Management 2015, pers. comm.; Johanson 2015, pers. comm.).

The NCCP/HCP planning process includes measures for managing coastal scrub vegetation, and current management is reducing the magnitude of the effects of type-conversion within the range of the coastal California gnatcatcher in the United States. Habitat is being added as managed reserves under the NCCP/HCPs at a pace that is roughly in keeping with habitat losses from urban development and other covered activities. However, the process is not yet complete for the decades-long permits issued for the NCCP/HCPs within the subspecies' range. In addition, management plans for each preserve area are not yet complete for these long-term plans, and ensuring sufficient resources for perpetual management of the reserves that addresses existing and future stressors, poses a challenge common to all regional NCCP/HCPs. These circumstances can lead to uncertainty regarding whether long-term management can adequately address vegetation type conversion in the future.

Therefore, vegetation type conversion represents a medium-level stressor leading to the destruction, modification, or curtailment of habitat or range of the coastal California gnatcatcher and causing long-term habitat alterations and impacts to gnatcatchers across the range of the subspecies. The best available scientific and commercial information indicates that vegetation type conversion will continue to have long-term impacts into the future.

Climate Change

Background

In this section, we consider observed or expected environmental changes resulting from ongoing and projected changes in climate. The effects of climate change were not addressed in detail in previous status reviews.

As defined by the Intergovernmental Panel on Climate Change (IPCC), the term "climate" refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2013a, p. 1,450). The term "climate change" thus refers to a change in the mean or the variability of relevant properties, which persists for an extended period, typically decades or longer, due to natural conditions (for example, solar cycles) or human-caused changes in the composition of atmosphere or in land use (IPCC 2013a, p. 1,450).

Scientific measurements spanning several decades demonstrate that changes in climate are occurring. In particular, warming of the climate system is unequivocal and many of the observed changes in the last 60 years are unprecedented over decades to millennia (IPCC 2013b, p. 4). The current rate of climate change may be as fast as any extended warming period over the past 65 million years and is projected to accelerate in the next 30 to 80 years (National Research Council 2013, p. 5). Thus, rapid climate change is adding to other sources of extinction pressures, such as land use and invasive species, which will likely place extinction rates in this era among just a handful of the severe biodiversity crises observed in Earth's geological record (American Association for the Advancement of Sciences (AAAS) 2014, p. 17).

Examples of various other observed and projected changes in climate and associated effects and risks, and the bases for them, are provided for global and regional scales in recent reports issued by the IPCC (2013c, entire; 2014, entire), and similar types of information for the United States and regions within it can be found in the National Climate Assessment (Melillo *et al.* 2014, entire).

Results of scientific analyses presented by the IPCC show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate and is "extremely likely" (defined by the IPCC as 95 to 100 percent likelihood) due to the observed increase in greenhouse gas (GHG) concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from fossil fuel use (IPCC 2013b, p. 17 and related citations).

Scientists use a variety of climate models, which include consideration of natural processes and variability as well as various scenarios of potential levels and timing of GHG emissions, to evaluate the causes of changes already observed and to project future changes in temperature and other climate conditions. Model results yield very similar projections of average global warming until about 2030; thereafter, the magnitude and rate of warming vary through the end of the century depending on the assumptions about population levels, emissions of GHGs, and other factors that influence climate change. Thus, absent extremely rapid stabilization of GHGs at a global level, there is strong scientific support for projections that warming will continue through the 21st century, and that the magnitude and rate of change will be influenced substantially by human actions regarding GHG emissions (IPCC 2013b, 2014; entire).

Global climate projections are informative, and in some cases, the only scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (for example, IPCC 2013c, entire; IPCC 2014, entire) and within the United States (Melillo *et al.* 2014, entire). Therefore, we use "downscaled" projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling).

Various changes in climate may have direct or indirect effects on a species. These may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as interactions of climate with other variables such as habitat fragmentation (for examples, see Franco *et al.* 2006; Forister *et al.* 2010; Galbraith *et al.* 2010; Chen *et al.* 2011; Bertelsmeier *et al.* 2013, entire). In addition to considering individual species, scientists are evaluating potential climate change-related impacts to, and responses of, ecological systems, habitat conditions, and groups of species (see, for example, Deutsch *et al.* 2008; Berg *et al.* 2010; Euskirchen *et al.* 2009; McKechnie and Wolf 2010; Sinervo *et al.* 2010; Beaumont *et al.* 2011; McKelvey *et al.* 2011; Rogers and Schindler 2011; Bellard *et al.* 2012).

Temperature

Regional temperature observations for assessing climate change are often used as an indicator of how climate is changing. The Western Regional Climate Center (WRCC) has defined 11 climate regions for evaluating various climate trends in California (Abatzoglou *et al.* 2009, p. 1,535). The relevant WRCC climate region for the distribution of the coastal California gnatcatcher in southern California is primarily the South Coast Region.

Three indicators of temperature, the increase in mean temperature, the increase in maximum temperature, and the increase in minimum temperature illustrate trends in climate change in California. For the South Coast Region, linear trends (evaluated over a 100-year time period) indicate an increase in mean temperatures (Jan–Dec) of approximately 2.65 °F (±0.49 °F) (1.47 ± 0.27 °C) since 1895 and 4.17 °F (±1.21 °F) (2.32 ± 0.67 °C) since 1949 (WRCC 2016, p. 6). Similarly, the maximum temperature 100-year trend for the South Coast Region shows an increase of about 1.94 °F (±0.52 °F) (1.08 ± 0.29 °C) since 1895 and 3.16 °F (±1.32 °F) (1.75 ± 0.73 °C) since 1949 (WRCC 2016, p. 9). Likewise, the minimum temperature 100-year trend for the South Coast Region shows an increase of about 3.37 °F (±0.52 °F) (1.87 ± 0.29 °C) since 1895 and 5.19 °F (±1.22 °F) (2.88 ± 0.68 °C) since 1949 (WRCC 2016, p. 12). It is reasonable to assume the rate of temperature increase for this region is higher for the second time period (since 1949) than for the first time period (since 1895) due to the increased use of fossil fuels in the 20th century. Even if that is not the mechanism, it is clear temperatures have increased in the South Coast Region since the start of data collection.

These observed trends provide information as to how climate has changed in the past. However, we must also consider whether and how climate may change in the future. Climate models can be used to simulate and develop future climate projections. Pierce *et al.* (2013, entire) presented both statewide and regional probabilistic estimates of temperature and precipitation changes for California (by the 2060s) using downscaled data from 16 global circulation models and 3 nested regional climate models. The study looked at a historical (1985–1994) and a future (2060–2069) time period using the IPCC Special Report on Emission Scenarios A2 (Pierce *et al.* 2013, p. 841). This IPCC-defined scenario was used for the IPCC's Third and Fourth Assessment reports, and it is based on a global population growth scenario and economic conditions that result in a relatively high level of atmospheric GHGs by 2100 (IPCC 2000, pp. 4–5; see also Stocker *et al.* 2013, pp. 60–68, and Walsh *et al.* 2014, pp. 25–28 for discussions and comparisons of the prior and current IPCC approaches and outcomes). Importantly, the projections by Pierce *et al.* (2013, pp. 852–853) include daily distributions and natural internal climate variability. Simulations using these downscaling methods project an increase in yearly temperature for the southern California coastal region ranging from 1.6 °C to 2.5 °C (2.9 °F to 4.5 °F) by the 2060s time period, compared to 1985–1994 (Pierce *et al.* 2013, p. 844). Averaging across all models and downscaling techniques, the simulations project a yearly-averaged warming of 2.1 °C (3.78 °F) by the 2060s (Pierce *et al.* 2013, p. 842).

Precipitation

Precipitation patterns can also be used as an indicator of how climate is changing. Killam *et al.* (2014, entire) evaluated trends in precipitation for 14 meteorological stations within all of California using annual precipitation data from the National Climatic Data Center. This study found an increasing trend in annual precipitation since 1925 for the northern and central regions of California and decreasing or minimal changes in southern California; however, none of the trends for these stations were significant (Killam *et al.* 2014, p. 171). The authors concluded that it is unclear as to whether there is a recognizable climate change signal in these precipitation records since annual variability in precipitation overwhelmed their observed trends, particularly precipitation patterns attributed to both the El Niño–Southern Oscillation and the Pacific decadal oscillation (multidecadal shifts in warm and cool phases in North Pacific sea surface temperatures) (Killam *et al.* 2014, p. 168).

Statewide and regional probabilistic estimates of precipitation changes for California were evaluated by Pierce *et al.* (2013, entire). Averaging across all models and downscaling methods, the simulations projected an annual mean decrease in precipitation for southern California (approximately 9 percent for the southern California coastal region) over the 2060–2069 time period compared to the mean over the 1985–1994 time period, but there was significant disagreement across the models (Pierce *et al.* 2013, pp. 849, 854).

Dynamic downscaled simulations indicate larger increases in summer (June–August) precipitation by the 2060s (as compared to statistical downscaling methods) within the region of California affected by the North America monsoonal flow (Pierce *et al.* 2013, pp. 851, 855). The North American monsoon is a regional-scale circulation that develops over the American Southwest during the months of July through September, affecting southern California and other locations in this region (Douglas *et al.* 2004, entire). Occasionally, hurricanes and tropical storms are captured in the monsoon circulation, which can result in heavy summer rains in the normally dry areas of the Southwest (Douglas *et al.* 2004, p. 11). As an example, from July 18–20, 2015, remnants of tropical storm Dolores, which had developed into a Category 4 hurricane off the coast of Baja California, generated record July rainfall amounts for several locations in southern California (Fritz 2015, entire). This storm and additional monsoonal-related rain events during the summer of 2015 in southern California were enhanced by higher than normal sea surface temperatures and the developing El Niño pattern in the Pacific Ocean (Serna and Lin 2015, p. B5).

Climate Change and Coastal California Gnatcatchers

The potential changes in climate described above are expected to have some effect on the coastal California gnatcatcher and its habitat. While the physical and biological mechanisms that result in the establishment of coastal scrub or chaparral vegetation are unclear, minimum temperatures, maximum temperatures, and precipitation (both amount and seasonality) within the southern California coastal region represent important influences on the subspecies and its habitat (Franklin 1998, p. 745). As noted above, there is little consensus on future trends in precipitation in southern California; however, it is highly likely that minimum and maximum temperatures will continue to rise. Malanson and O'Leary (1995, p. 219) suggested that higher average temperatures in the future may create an upslope shift in coastal scrub vegetation into areas that are currently occupied by chaparral. This may expand or shift areas that currently provide suitable habitat for coastal California gnatcatchers. Similarly, because the subspecies' distribution is thought to be limited by low temperatures (Mock 1998, p. 415), warmer minimum temperatures may also allow for coastal California gnatcatchers to survive at higher elevations, thereby allowing the subspecies to extend its range into areas previously not occupied (Preston *et al.* 2008, p. 2,512). In contrast, climate change may affect nutrient cycling (Allen *et al.* 1995, entire) or may promote a wildland fire regime with increased fire frequency (Batllori *et al.* 2013, entire); both of these effects would create conditions more favorable for vegetation type conversion to nonnative annual grassland, which would be unsuitable habitat for coastal California gnatcatchers.

Climate Change Summary

Climate change due to global warming is influencing regional climate patterns that may result in changes to the habitat for the coastal California gnatcatcher into the mid-21st century (approximately 2060s). While climate change may expand or shift the coastal California gnatcatcher's preferred habitat of coastal scrub vegetation in some areas, it may also create conditions more favorable for vegetation type conversion to unsuitable habitat such as nonnative annual grasslands. The best available regional data on current and potential future trends related to climate change, within the range of the coastal California gnatcatcher, indicate that the effects of climate change is a low- to medium-level stressor at the present time that is anticipated to result in shifts to the distribution of the subspecies' habitat and that may potentially affect gnatcatchers at the individual or population level. Based on model projections, we can reliably predict these changes will continue into the mid-21st century (2060s).

Disease

Two diseases have been identified as potential threats to the coastal California gnatcatcher, West Nile virus and Newcastle disease. These are discussed in greater detail in our 2010 5-year review where we concluded that disease was not a significant threat to the subspecies (Service 2010, pp. 21–22). Because known West Nile virus cases and the range of the coastal California gnatcatcher overlap geographically, the subspecies has likely been exposed to West Nile virus. While new information suggests that the impact to birds in North America has been widespread (George *et al.* 2015, entire), we have no evidence of detection of West Nile virus in the coastal California gnatcatcher and no information indicating that this disease has caused any decline in coastal California gnatcatcher populations. Furthermore, Newcastle disease does not appear to have affected gnatcatchers (Service 2010, p. 22). In summary, there is no evidence that disease is a stressor at the present time to the coastal California gnatcatcher, nor do we expect it to be into the future.

Predation

The effects of predation on the coastal California gnatcatcher are discussed in greater detail in our 2010 5-year review, where we concluded that predation is not a significant threat to the subspecies (Service 2010, pp. 22–24). Predation undoubtedly occurs among all life stages of the coastal California gnatcatcher, but only nest predation has been previously identified as affecting recruitment and survival at levels that could have potential effects on the population (such as reduction in fledging success). Nest predation rates for the coastal California gnatcatcher are higher than most open-nesting passerines because they occupy a naturally predator-rich environment (Service 2010, p. 23). However, the life-history strategy of the coastal California gnatcatcher allows pairs to re-nest repeatedly, compensating for this potential stressor. Therefore, we conclude that predation continues to represent a low-level impact to the subspecies that affects individual pairs of gnatcatchers, but it is not having a population-level impact at the present time, and this situation is not expected to change into the future.

Fragmentation

Fragmentation represents a suite of stressors that affect a species at various levels and scales. At its simplest, it involves a large, continuous block of habitat being broken up into smaller pieces, which become isolated from each other within a mosaic of other habitats. It is, therefore, not unrelated to habitat destruction and type conversion (see the *Urban and Agricultural Development* section and *Vegetation Type Conversion* sections above). However, changes in proximity to unsuitable habitat, distance to other areas of suitable habitat, size of habitat, and the length of time a fragment has been isolated may all have negative impacts on individuals of the species, such as increased predation rates, genetic isolation, or increased risk of local extirpation.

As discussed in our 2010 5-year review, the coastal California gnatcatcher is not particularly sensitive to edge or distance effects (Service 2010, p. 32). This characteristic is further supported by new information indicating that populations of coastal California gnatcatchers within the United States are fairly well connected over large areas. However, some populations (for example, the Palos Verdes Peninsula, greater Ventura County, and Coyote Hills populations) are currently separated by large distances by areas of non-habitat and, therefore, are not as well connected with the populations in the rest of southern California (Vandergast *et al.* 2014, pp. 8–9). We also noted in the 2010 5-year review (Service 2010, p. 32) that the coastal California gnatcatcher appeared to be somewhat susceptible to the effects associated with small fragment size (area), but new information suggests otherwise (Winchell and Doherty 2014, p. 543). Our concern at that time was that small areas of habitat would not support coastal California gnatcatchers over time and that the loss of the gnatcatcher population in a given (small) patch would be permanent. While a given patch of suitable coastal California gnatcatcher habitat may not always be occupied by the subspecies, these patches of habitat can be recolonized over time (Winchell and Doherty 2014, p. 543). Winchell and Doherty (2014, p. 543) also found that coastal California gnatcatchers gradually recolonize a regrowing burned area from the perimeter inwards (see *Wildland Fire* section above), which indicates that coastal California gnatcatchers have some level of sensitivity to spatial and temporal elements in habitat fragments.

Ongoing and anticipated implementation of regional NCCP/HCPs is expected to create a network of core-and-linkage habitat areas, thereby preventing or reducing the effects of future habitat fragmentation for much of the U.S. range of the coastal California gnatcatcher. The core areas are large, mostly unfragmented areas, while linkage areas are intended to provide continuous or "stepping stone" corridors for coastal California gnatcatcher movement and dispersal. Thus, as indicated by new information from Vandergast *et al.* (2014, entire) and Winchell and Doherty (2014, entire), the ability of the coastal California gnatcatcher to move between and recolonize habitat areas within the U.S. range, including the existing preserve-and-linkage areas, helps to reduce some of the effects associated with habitat fragmentation, although connectivity remains somewhat limited at the larger scales.

The new information we have received since the 2010 5-year review suggests that fragmentation is a threat of lower magnitude than was described at the time of listing. However, the effects of fragmentation are more significant than previously recognized for those coastal California gnatcatcher populations that have become widely separated due to urban development and other habitat losses or modifications (for example, wildland fire), particularly the geographically isolated populations in Ventura County, Palos Verdes (western Los Angeles County), and Coyote Hills (northern Orange County) (Vandergast *et al.* 2014, pp. 8, 12). Therefore, we consider the effects of fragmentation to represent a low- to medium-level stressor to the subspecies within portions of its range, and we can reliably predict that this level of stressor will continue into the future.

Brood Parasitism

Rates of brood parasitism by invasive, nonnative brown-headed cowbirds (*Molothrus ater*) appear to vary throughout the range of the coastal California gnatcatcher, depending upon nearby land uses (for example, higher rates of brood parasitism near livestock and agriculture). Because brown-headed cowbirds are thought to have invaded coastal southern California during the 20th century, any rate of brood parasitism exceeds the historical rate of parasitism. However, the re-nesting behavior of the coastal California gnatcatcher following a failed nesting attempt enables individual birds to reduce the magnitude of this threat, as opposed to some migratory songbirds that do not re-nest as readily. Additionally, cowbird trapping has been found to be an effective tool and has helped to reduce impacts to the coastal California gnatcatcher (as informed by monitoring) within many of the reserves established under regional NCCP/HCPs (Service 2010, p. 33). Additionally, certain ESA section 10(a)(1)(A) permit holders may be authorized to conduct coastal California gnatcatcher nest monitoring activities that may include the removal of brown-headed cowbird chicks and eggs (with minimal disturbance to nesting gnatcatchers). At the discretion of the permittee, these activities may further include replacement of cowbird eggs with dummy eggs to preclude the abandonment of small clutches. These activities help to decrease the impact of cowbird parasitism on individual coastal California gnatcatchers. Given the subspecies' ability to re-nest following nest failure along with ongoing management, we conclude brood parasitism is a low- to medium-level stressor affecting some populations of coastal California gnatcatchers throughout the subspecies' range in the United States, and we expect this level of stressor will continue into the future. We have no specific information on the impact of brown-headed cowbirds on coastal California gnatcatcher populations in Mexico, but brown-headed cowbirds occur as a breeding species along the length of the Baja California peninsula (see Erickson *et al.* 2007, p. 583), including throughout the range of the coastal California gnatcatcher. We expect that the level of impact of this stressor in Mexico is similar to that in unmanaged areas of the United States.

Existing Regulatory Mechanisms

Existing regulatory mechanisms that affect the coastal California gnatcatcher include laws and regulations promulgated by Federal and State governments in the United States and in Mexico. In relation to *Factor D* under the Act, we consider relevant Federal, State, and Tribal laws, regulations, and other such mechanisms that may minimize any of the threats we describe under the other four factors, or otherwise enhance conservation of the species. We give strongest weight to statutes and their implementing regulations and to management direction that stems from those laws and regulations; an example would be State governmental actions enforced under a State statute or constitution, or Federal action under statute. For currently listed species, we consider the adequacy of existing regulatory mechanisms to address threats to the species absent the protections of the Act. Potential threats acting on the coastal California gnatcatcher for which governments may have regulatory control include impacts associated with urban and agricultural development, vegetation type conversion, wildland fire, climate change, and brood parasitism.

Federal Mechanisms

National Environmental Policy Act (NEPA)

All Federal agencies are required to adhere to the NEPA of 1970 (42 U.S.C. 4321 *et seq.*) for projects they fund, authorize, or carry out. Prior to implementation of such projects with a Federal nexus, NEPA requires the agency to analyze the project for potential impacts to the human environment, including natural resources. However, NEPA does not impose substantive environmental obligations on Federal agencies—it merely prohibits an uninformed agency action. Although NEPA requires full evaluation and disclosure of information regarding the effects of contemplated Federal actions on sensitive species and their habitats, it does not by itself regulate activities that might affect the coastal California gnatcatcher; that is, effects to the subspecies and its habitat would receive the same scrutiny as other plant and wildlife resources during the NEPA process and associated analyses of a project's potential impacts to the human environment.

Endangered Species Act of 1973, as Amended (Act)

Upon its listing as threatened, the coastal California gnatcatcher benefited from the protections of the Act, which include the prohibition against take and the requirement for interagency consultation for Federal actions that may affect the species. Section 9 of the Act and Federal regulations prohibit the take of endangered and threatened species without special exemption. The Act defines "take" as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). Our regulations define "harm" to include significant habitat modification or degradation that results in death or injury to listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). Our regulations also define "harass" as intentional or negligent actions that create the likelihood of injury to a listed species by annoying it to such an extent as to significantly disrupt normal behavior patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

Section 7(a)(1) of the Act requires all Federal agencies to utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of endangered species and threatened species. Section 7(a)(2) of the Act requires Federal agencies to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of listed species or destroy or adversely modify their critical habitat. Because the Service has regulations that prohibit take of all threatened wildlife species (50 CFR 17.31(a)), unless modified by a rule issued under section 4(d) of the Act (50 CFR 17.31(c)), the regulatory protections of the Act are largely the same for wildlife species listed as endangered and as threatened.

A section 4(d) rule for the coastal California gnatcatcher was published on December 10, 1993 (58 FR 65088). Under that rule, incidental take of the coastal California gnatcatcher is not considered to be a violation of section 9 of the Act if the take results from activities conducted pursuant to the NCCP Act of 1991 and in accordance with an approved NCCP plan, provided that the Service determines that such a plan meets the issuance criteria of an "incidental take" permit pursuant to section 10(a)(2)(B) of the Act and 50 CFR 17.32(b)(2). Under the section 4(d) rule, a limited amount of incidental take of the coastal California gnatcatcher within subregions actively engaged in preparing a NCCP plan will also not be considered a violation of section 9 of the Act, provided the activities resulting in such take are conducted in accordance with the NCCP Conservation Guidelines and Process Guidelines. Under section 10(a)(1)(B) of the Act, the Service may issue permits authorizing the incidental take of federally listed animal species. Incidental take permittees must develop and implement a habitat conservation plan (HCP) that minimizes and mitigates the impacts of take to the maximum extent practicable and that avoid jeopardy to listed species. Incidental take permits are available to private landowners, corporations, Tribal governments, State and local governments, and other non-Federal entities. These permits can reduce conflicts between endangered species and economic activities and develop important partnerships between the public and private sectors. As discussed in the *Urban and Agricultural Development* section above, we have issued incidental take permits for regional HCP and HCP/NCCPs covering approximately 59 percent of modeled gnatcatcher habitat, and two additional HCP/NCCPs are nearing completion.

Since 1993, the Service has addressed impacts to the coastal California gnatcatcher from urban development and other projects outside of the NCCP/HCP regional planning effort through the section 7 process. The projects have included residential and commercial developments, highway-widening projects, and pipeline projects, among others. Section 7 consultations have also been conducted with the U.S. Army Corps of Engineers for Clean Water Act permit applications, and other Federal agencies on specific actions. In addition to "projects," we have consulted with the U.S. Marine Corps to address potential impacts to the gnatcatcher and its habitat from military training activities on Marine Corps Base Camp Pendleton (Camp Pendleton) and Miramar Corps Air Station (Miramar), and we have consulted with the U.S. Navy on actions related to the management of Naval Weapons Station Seal Beach Detachment Fallbrook (Detachment Fallbrook).

We reviewed the number of formal section 7 consultations for the coastal California gnatcatcher in our Tracking and Integrated Logging System (TAILS) database (initiated in 2007) that were completed from 1996 through March 2016. In total, the Carlsbad and Ventura Fish and Wildlife Offices completed 320 formal consultations during that time period (Service 2016b). In all of these consultations, we concluded that, due to the implementation of conservation measures to avoid, minimize, and offset impacts to the subspecies and its habitat, effects of the proposed actions were not likely to jeopardize the continued existence of the coastal California gnatcatcher and were not likely to result in the destruction or adverse modification of designated critical habitat for the subspecies. We will continue to evaluate impacts of proposed projects to the subspecies and its habitat for those areas outside of the NCCP/HCPs through other provisions of the Act, such as section 7 consultation, recovery implementation, and periodic status reviews.

Our evaluation confirms that urban development and associated threats continue for the coastal California gnatcatcher, but listing of the coastal California gnatcatcher under the Act as threatened has provided protection to the subspecies and its habitat, including the prohibition against take and the conservation mandates of section 7 for all Federal agencies.

Sikes Act

The Sikes Act (16 U.S.C. 670a–670f, as amended) directs the Secretary of Defense, in cooperation with the Service and State fish and wildlife agencies, to carry out a program for the conservation and rehabilitation of natural resources on military installations. The Sikes Act Improvement Act of 1997 (Pub. L. 105–85) broadened the scope of military natural resources programs, integrated natural resources programs with operations and training, embraced the tenets of conservation biology, invited public review, strengthened funding for conservation activities on military lands, and required the development and implementation of an Integrated Natural Resources Management Plan (INRMP) for relevant installations, which are reviewed every 5 years.

INRMPs incorporate, to the maximum extent practicable, ecosystem management principles, provide for the management of natural resources (including fish, wildlife, and plants), allow multipurpose uses of resources, and provide public access necessary and appropriate for those uses without a net loss in the capability of an installation to support its military mission. An INRMP is an important guidance document that helps to integrate natural resource protection with military readiness and training. In addition to technical assistance that the Service provides to the military, the Service can enter into interagency agreements with installations to help implement an INRMP. The INRMP implementation projects can include wildlife and habitat assessments and surveys, fish stocking, exotic species control, and hunting and fishing program management.

On Department of Defense lands, including Camp Pendleton, Detachment Fallbrook, and Miramar, coastal California gnatcatcher habitat is generally not subjected to threats associated with large-scale development. However, the primary purpose for military lands, including most gnatcatcher habitat areas, is to provide for military support and training. At these installations, INRMPs provide direction for project development and for the management, conservation, and rehabilitation of natural resources, including for the subspecies and its habitat. For example, on Camp Pendleton and MCAS Miramar, management measures that benefit the coastal California gnatcatcher and its habitat include nonnative vegetation control, nonnative animal control, and habitat enhancement and restoration (MCB Camp Pendleton 2007, p. F–25; MCAS Miramar INRMP 2010, pp. 7–18–7–19). Some restrictions on training and construction activities also apply during gnatcatcher breeding season to reduce impacts on nesting gnatcatchers (MCB Camp Pendleton 2007, p. F–25; MCAS Miramar INRMP 2010, pp. 7–18–7–19).

Without the protections provided to the subspecies and its habitat under the Act (that is, if the coastal California gnatcatcher was delisted), there would be less incentive for the Marine Corps or Navy to continue to include specific provisions (for example, monitoring) in their INRMPs to provide conservation benefits to the subspecies, beyond that provided under a more general integrated natural resource management strategy at these and other DOD installations.

State Laws Affecting the Coastal California Gnatcatcher

The coastal California gnatcatcher is designated as a Species of Special Concern by the California Department of Fish and Wildlife (CDFW) (CDFG 2008). Although this designation is administrative and provides no formal legal status for protection, it is intended to highlight those species at conservation risk to State and Federal and local governments, land managers, and others, as well as to encourage research for those species whose life history and population status are poorly known (Comrack *et al.* 2008, p. 2).

California Environmental Quality Act (CEQA)

CEQA (California Public Resources Code 21000–21177) is the principal statute mandating environmental assessment of projects in California. The purpose of CEQA is to evaluate whether a proposed project may have an adverse effect on the environment and, if so, to determine whether that effect can be reduced or eliminated by pursuing an alternative course of action, or through mitigation. CEQA applies to certain activities of State and local public agencies; a public agency must comply with CEQA when it undertakes an activity defined under CEQA as a "project."

As with NEPA, CEQA does not provide a direct regulatory role for the CDFW or other State and local agencies relative to activities that may affect the coastal California gnatcatcher. However, CEQA requires a complete assessment of the potential for a proposed project to have a significant adverse effect on the environment. Among the conditions outlined in the CEQA Guidelines that may lead to a mandatory finding of significance are where the project "has the potential to . . . substantially reduce the habitat of a fish or wildlife species; cause a fish or wildlife population to drop below self-sustaining levels; threaten to eliminate a plant or animal community; [or] substantially reduce the number or restrict the range of an endangered, rare or threatened species" (title 14 of the California Code of Regulations (CCR), § 15065(a)(1)). The CEQA Guidelines further state that a species "not included in any listing [as threatened or endangered] shall nevertheless be considered to be endangered, rare, or threatened, if the species can be shown to meet the criteria" for such listing (14 CCR 15380(d)). In other words, CEQA would require any project that may impact populations of these species to assess and disclose such potential impacts during the environmental review process (Osborn 2015, pers. comm.).

The Natural Community Conservation Planning (NCCP) Act

The NCCP program is a cooperative effort between the State of California and numerous private and public partners with the goal of protecting habitats and species. The NCCP program identifies and provides for the regional or area-wide protection of plants, animals, and their habitats while allowing compatible and appropriate economic activity. The program uses an ecosystem approach to planning for the protection and continuation of biological diversity (*https://www.wildlife.ca.gov/Conservation/Planning/NCCP*). Regional NCCPs provide protection to federally listed and other covered species by conserving native habitats upon which the species depend. NCCPs are usually developed in conjunction with habitat conservation plans (HCPs) prepared pursuant to the Act.

The 2010 5-year review discusses the NCCP program in greater detail. Currently, the following NCCP plans that cover the coastal California gnatcatcher are approved and being implemented: Multiple Species Conservation Program (one of four Subregional Plans in San Diego County with 5 of 11 Subarea Plans approved), San Diego County Water Authority NCCP/HCP, San Diego Gas & Electric NCCP, San Diego Multiple Habitat Conservation Program (a second Subregional Plan in San Diego County with 1 of 6 Subarea Plans approved), Western Riverside County Multiple Species Habitat Conservation Plan (Western Riverside County MSHCP), and Orange County Central/Coastal NCCP/HCP (CDFW 2015, pp. 12 and 13). Additionally, the Orange County Transportation Authority M2 NCCP/HCP in Orange County and the Rancho Palos Verdes NCCP/HCP in Los Angeles County are nearing completion. The North County Multiple Species Conservation Plan and the East County Multiple Species Conservation Plan (CDFW 2015, pp. 12 and 13), the third and fourth Subregional Plans in San Diego County, are still in the development phase. Finally, the Orange County Southern Subregion HCP is not approved as an NCCP, but this plan is a regionally significant Service-approved HCP that includes core populations of the coastal California gnatcatcher and large expanses of coastal sage scrub.

These plans provide a comprehensive, habitat-based approach to the protection of covered species, including the coastal California gnatcatcher, by focusing on lands identified as important for the long-term conservation of the covered species and through the implementation of management actions for conserving those lands. These protections are outlined in the management actions and conservation objectives described within each plan. However, because the total habitat protection associated with these plans is not expected until plans are fully implemented, and because not all areas are covered, habitat loss is still impacting the gnatcatcher and is expected to continue into the future.

In our 2010 5-year review, we estimated that 59 percent of modeled coastal California gnatcatcher habitat in the United States would be conserved with full implementation of currently permitted, long-term Regional NCCP/HCPs (Service 2010, p. 15). We reviewed the most currently available reports for four regional NCCP/HCPs and one HCP to determine the amount of coastal sage scrub habitat that has been conserved as of the date of the respective final reports:

- For the San Diego County MSCP (City of San Diego, County of San Diego, City of Chula Vista, City of Poway, and City of La Mesa), the total number of acres of coastal sage scrub habitat conserved both inside and outside the preserve planning area is 49,871 ac (20,182 ha); conserved habitat inside the preserve planning area is approximately 42,129 ac (17,049 ha) or about 68 percent of the plan's target (City of Chula Vista 2015, p. 35; City of San Diego 2015, p. 15; County of San Diego 2015, p. 51).
- For the San Diego County MSCP, the City of Carlsbad reported 1,683 ac (681 ha) of coastal sage scrub conserved within their Habitat Management Preserve system as of December 2015 (84 percent of target) (Grim 2016, pers. comm.).
- For the Orange County Central—Coastal NCCP/HCP (as of the end of 2013), the amount of coastal sage scrub conserved is 17,809 ac (7,207 ha) (Nature Reserve of Orange County 2013).
- For the Western Riverside County MSHCP, the Western Riverside County Regional Conservation Authority (WRCRCA 2015, pp. 3–9—3–10) reported that 11,802 ac (4,776 ha) of coastal sage scrub was conserved from February 2000 to December 31, 2013.

With the addition of the Orange County Southern Subregion HCP, which reported coastal California gnatcatcher scrub habitat of 13,135 ac (5,315 ha) within reserves as of December 2013 (Rancho Mission Viejo 2013), the total number is approximately 86,558 ac (35,028 ha) of coastal sage scrub conserved (within reserves established by these plans). This amount represents about 47 percent of the total target (182,976 ac (74,048 ha)) of coastal California gnatcatcher habitat to be preserved by the five plans described in our 2010 5-year review (Service 2010, p. 15).

In summary, while conservation is anticipated to continue within existing plan boundaries within the U.S. range of the coastal California gnatcatcher, habitat protection occurs in a step-wise fashion as areas are conserved, and the total habitat protection associated with a plan is not expected until plans are fully implemented. Once the plans are fully implemented upon completion of the permits (which last for 50–75 years), the plans would provide conservation for much of the 56 percent of the coastal California gnatcatcher's range in the United States. However, the 44 percent of the subspecies range in Baja California is not subject to protections provided by NCCP/HCP plans. Therefore, the subspecies and its habitat remain susceptible to urban development and associated threats.

Without the protections provided to the subspecies and its habitat under the Act (that is, if the coastal California gnatcatcher was delisted), the current NCCP/HCPs may provide some ancillary benefits to the subspecies given that other federally listed species of plants and animals covered under these plans are also found within coastal sage scrub habitat (for example, Quino checkerspot butterfly (*Euphydrays editha quino*)). By continuing to implement the plans, the permittees would retain incidental take coverage for these other species. However, permittees under these regional plans could request permit modifications or request that their long-term permits be renegotiated should the coastal California gnatcatcher be delisted under the Act. Similarly, the NCCP/HCPs currently under development in southern California would likely require reevaluation. However, all conservation already implemented would continue to provide benefits to the coastal California gnatcatcher even if it was delisted. Because conservation and management for the coastal California gnatcatcher has not yet been fully implemented under the NCCP/HCPs in place and some NCCP/HCPs are not yet developed, all of the potential conservation anticipated under these plans is not yet fully assured absent the protections of the Act.

Regulatory Mechanisms in Mexico

As described above (see *Urban and Agricultural Development* section), we recently estimated that approximately 1,704,406 ac (689,749 ha) of coastal sage scrub habitat remains in Baja California from 30 °N. to the United States-Mexico border (Service 2016a).

The Mexican Government recognizes the *atwoodi* subspecies of the California gnatcatcher (see taxonomic classification of Mellink and Rea 1994, pp. 59–62); Mellink and Rea (1994, p. 55) described *Polioptila californica atwoodi* as a new subspecies of California gnatcatcher from northwestern Baja California, Mexico. They defined a range for this novel subspecies as "from Rio de las Palmas and Valle de las Palmas (30 km SE. of Tijuana) in the interior and at least Punta Banda along the coast south to Arroyo El Rosario, 32 to 30 °N." within coastal sage scrub and maritime succulent scrub plant communities (Mellink and Rea 1994, p. 55); this distribution mostly overlaps with what the Service considers to be the listed gnatcatcher subspecies (58 FR 16742; March 30, 1993).

This entity is listed as threatened under Mexico's *NORMA Oficial Mexicana* NOM–059–SEMARNAT–2010, Environmental Protection—Species of Wild Flora and Fauna Native to Mexico (*Protección ambiental—Especies nativas de México de flora y fauna silvestres—Categorías de riesgo y* *especificaciones para su inclusión, exclusión o cambio—Lista de especies en riesgo*) (SEMARNAT 2010). Threatened species are defined under Mexican law as those which may be "in danger of disappearing in the short or medium term" if factors that adversely affect their viability, such as deterioration or modification of habitat, or directly reduce the size of their populations, continue to operate (SEMARNET 2010, p. 5). However, enforcement of this law generally depends upon an individual or a groups' willingness to modify proposed projects rather than the legal protections provided under the law (Hinojosa 2008, pers. comm.). Monitoring of compliance with this law is the responsibility of the *Secretaria de Medio Ambiente y Recursos Naturales* through its established entities. We do not have further information regarding the effectiveness of this law for protecting the coastal California gnatcatcher and its habitat.

In Mexico, the development of state and municipal plans is designed to regulate and control land use and various production activities as well as provide environmental protections and preservation and sustainability of natural resources (Conservation Biology Institute 2004, p. 31). As an example, an *ordenamiento ecológico* (ecological regulation/zoning ordinance) is being developed for the City of Tijuana to identify *áreas verdes* (important natural resource areas), and the *ordenamiento* will be used to guide land development within Tijuana (Conservation Biology Institute 2004, p. 31). Other State and Federal environmental laws in Mexico include *Ley General del Equilibrio Ecológico y la Protección al Ambiente* and *Ley de Protección al Ambiente para el Estado de Baja California,* which require the preparation of an environmental impact study (*manifestación de impacto ambiental*) for any development project; if the project is determined to result in negative environmental impacts, the developer must undertake mitigation actions to minimize these impacts and/or restore natural conditions (Conservation Biology Institute 2004, p. 31).

Existing Regulatory Mechanisms Summary

Outside of the Act, few Federal conservation management and conservation measures exist throughout the U.S. range of the coastal California gnatcatcher that provide protections to the subspecies and its habitat. State management and conservation measures are limited primarily to the planning and implementation of the NCCP Act, and there is uncertainty as to whether the regional plans would continue to provide the full conservation benefits anticipated should the subspecies be delisted under the Act. Limited protection is provided to the coastal California gnatcatcher through the inclusion of its designation as a Species of Special Concern within State (CEQA) planning processes.

Based on the best available data, the listing of the *atwoodi* subspecies of the California gnatcatcher by the Mexican Government provides a limited level of protection or conservation benefit to the *atwoodi* populations found in Baja California. Comprehensive reserve areas for coastal sage scrub and chaparral vegetation have not been established in northern Baja California. While existing Mexican regulatory mechanisms may provide some protection for the subspecies, we lack information on implementation of those mechanisms specifically related to protection of the coastal California gnatcatcher, protection of habitat, and abatement of threats.

Therefore, although regulatory mechanisms are in place and provide some protection to the coastal California gnatcatcher and its habitat throughout its range, absent the protections of the Act (for example, section 7, section 9, and section 10(a)(1)(B)), these mechanisms would provide substantially less protection from the stressors currently acting on the subspecies such as urban and agricultural development. Moreover, some of the threats faced by the species and its habitat, including wildland fire, vegetation type conversion, and fragmentation, are not readily susceptible to amelioration through regulatory mechanisms.

Cumulative Effects

Threats can work in concert with one another to cumulatively create conditions that may impact the coastal California gnatcatcher or its habitat beyond the scope of each individual threat. The best available data indicate that cumulative impacts are currently occurring from the combined effects of a number of stressors, including vegetation type conversion, wildland fire, and the effects of climate change.

These stressors interact in multiple ways. As discussed in the *Wildand Fire* section above, the wildland fire-type conversion feedback loop promotes the degradation and eventual loss of coastal California gnatcatcher habitat, especially on a local scale where there are short intervals between fires (Service 2010, pp. 15–18). The effects associated with climate change have the potential to further contribute to the vegetation type conversion process, though it is not yet clear how climate change will interact with the ongoing conversion of coastal sage scrub to nonnative grasses and other vegetation types unsuitable for use by the coastal California gnatcatcher. It is also unclear whether it will increase or decrease the rate of change.

Furthermore, based on our analysis of the best available data, it is likely that the native plant communities that support the coastal California gnatcatcher in southern California are presently impacted by the cumulative effects of wildland fire and the warming effects of climate change. Yue *et al.* (2014, entire) developed projections of wildfire activity in southern California at mid-century (2016–2065) using the IPCC's A1B scenario (moderate growth in fossil fuel emissions in the first half of the 21st century but with a gradual decrease after 2050). Using regression models, the study found a likely doubling of area burned in southwestern California by midcentury, while parameterization models indicate a likely increase of 40 percent in this region under this IPCC scenario (Yue *et al.* 2014, p. 1,973). The analysis was unique in that the models considered the effects of future patterns of Santa Ana wind events. It indicates that a projected midcentury increase in November Santa Ana wind events will contribute to the increased area burned at that time of year (Yue *et al.* 2014, p. 1,990). The authors conclude that the results suggest that wildfire activity will likely increase in southwestern California due to rising surface temperatures (Yue *et al.* 2014, p. 1,989).

Stavros *et al.* (2014, entire) developed regional projections of the probability of very large wildland fires (defined as greater than or equal to 50,000 ac (20,234 ha)) under various climate change scenarios for the western United States. Their model results found a significant increase in the likelihood and frequency of very large fires for climate regimes projected in 2031–2060, relative to 1950–2005, in almost all areas, including southern California (Stavros *et al.* 2014, p. 460). These impacts are expected to continue into the future (to the 2060s based on climate change projections).

The climate change-wildland fire connection will likely result in a reduction in the amount of suitable habitat for the coastal California gnatcatcher and will likely lead to a greater chance of vegetation type conversion that degrades and eventually eliminates coastal California gnatcatcher habitat. Moreover, these stressors, working singly or in combination, are operating at a landscape scale. These stressors may affect large areas and may not be addressed by current management plans. Thus, in the absence of management to counteract the identified effects, these stressors are contributing to the habitat-degradation and type-conversion continuum that is occurring throughout the range of the subspecies. Therefore, as summarized above and as described in our 2010 5-year review, the best available data indicate that the cumulative effects of vegetation type conversion, wildland fire, and climate change will continue to act as a high-level stressor on the coastal California gnatcatcher and its habitat now and into the future.

Finding

In making this finding, we have followed the procedures set forth in section 4(a)(1) of the Act and regulations implementing the listing provisions of the Act in 50 CFR part 424. We reviewed the petition, information available in our files, and other available published and unpublished information. We sought input from subject matter experts and other Federal, State, and Tribal agencies. On the basis of the best scientific and commercial information available, we find that the petitioned action to delist the coastal California gnatcatcher is not warranted. Review of the best available scientific and commercial data did not show that the original determination, made at the time the species was classified as threatened in 1993, is now in error. Rather, using a multi-evidence criteria approach, the best available scientific and commercial data supports the coastal California gnatcatcher as a valid (distinguishable) subspecies.

For the purposes of our status review, as required by the Act, we considered the five factors in assessing whether the coastal California gnatcatcher is endangered or threatened throughout all of its range. In our threats analysis, we examined the best scientific and commercial information available regarding the past, present, and foreseeable future threats faced by the subspecies. We reviewed the information available in our files, information submitted by the public in response to our 90-day finding (79 FR 78775; December 31, 2014), and other available published and unpublished information. As described above in Background, the petitioners did not provide any new information on any of the factors. Based on our review of the best available scientific and commercial information, we find that the current and future threats are of sufficient imminence, intensity, or magnitude to indicate that the coastal California gnatcatcher remains likely to become an endangered species within the foreseeable future throughout all of its range. Therefore, the coastal California gnatcatcher currently meets the definition of a threatened species.

We evaluated each of the potential stressors discussed in the 2010 5-year review (Service 2010, entire), and we determined the following factors have impacted the coastal California gnatcatcher and its habitat or may affect gnatcatcher individuals or populations in the future: Urban and agricultural development (*Factor A*), grazing (*Factor A*), wildland fire (*Factor A* and *Factor E*), vegetation type conversion (*Factor A*), climate change (*Factor A* and *Factor E*), disease (*Factor C*), predation (*Factor C*), fragmentation (*Factor A* and *Factor E*), and brood parasitism (*Factor E*). Disease (*Factor C*) and predation (*Factor C*) are having only local, small-scale impacts to the coastal California gnatcatcher and its habitat throughout its range; therefore, we do not consider disease or predation to be threats at this time.

Additionally, though brood parasitism (*Factor E*) is affecting individual coastal California gnatcatcher pairs throughout the species' range, the impacts in the United States are being reduced through available regulatory mechanisms and implementation of conservation measures, such as regional NCCP/HCP management plans and section 10(a)(1)(A) permits. Furthermore, the ability of the coastal California gnatcatcher to re-nest multiple times in one breeding season helps it to be resilient to brood parasitism by brown-headed cowbirds. Therefore, we do not find that brood parasitism poses a threat to the coastal California gnatcatcher at the present time, nor do we expect it to become a threat in the foreseeable future.

At this time, impacts from urban and agricultural development (*Factor A*) continue to be a medium- to high-level stressor for the coastal California gnatcatcher and its habitat. Implementation of existing HCPs and the ongoing development of additional NCCP/HCPs have significantly reduced the impacts of urban development to coastal California gnatcatcher habitat in the United States; however, none of the regional plans are fully implemented. We estimated that these plans encompass approximately 55 percent of coastal sage scrub habitat and that approximately 47 percent of the plans' conservation targets have been reached (Service 2016a), for a total of 28 percent of habitat conserved overall in the U.S. range of the subspecies by NCCP/HCP plans. Though we anticipate that additional habitat will be conserved with full implementation of the existing plans, total conservation of the areas identified within the plans is not expected until the plans are fully implemented. Overall, 49 percent of coastal sage scrub in the United States has no mechanism preventing conversion of the habitat for urban or agricultural uses (Service 2016a), and Mexico has few areas of coastal sage scrub protected from development. Therefore, though substantial progress has been made since the time of listing to conserve habitat that supports the coastal California gnatcatcher, we find that urban and agricultural development continues to pose a threat to the coastal California gnatcatcher and its habitat.

Though grazing (*Factor A*) is having only low-level impacts to coastal California gnatcatcher habitat in the United States, grazing in coastal scrub habitat in Mexico can still result in vegetation type conversion, and land clearing for grazing purposes has been documented within northern Baja California. Therefore, we find that grazing is posing a threat to the subspecies' habitat in Mexico, though habitat impacts can be temporary.

Wildland fire (*Factor A* and *Factor E*) was identified as a threat to the coastal California gnatcatcher and its habitat both at the time of listing and in our 2010 5-year review. Based on our analysis, although currently established NCCP/HCPs provide for the establishment of coastal sage scrub reserves and include fire management as one of their primary objectives, there is no mechanism or conservation measure that can fully prevent the recurrence of natural or human-caused destructive wildland fires in coastal California gnatcatcher habitat. Therefore, we find that wildland fire poses a threat to the coastal California gnatcatcher and its habitat throughout the range of the species and that this threat will continue to cause impacts into the foreseeable future.

Vegetation type conversion (*Factor A*) of coastal sage scrub to nonnative grasslands is ongoing throughout the range of the coastal California gnatcatcher. Effects of type conversion are currently being reduced through habitat management by NCCP/HCPs; however, management plans for each reserve area are not yet complete, and maintaining adequate funding for perpetual management of the reserves is a challenge common to all regional NCCP/HCPs. Therefore, vegetation type conversion is posing a threat to the coastal California gnatcatcher and its habitat, and we expect that these impacts will continue into the foreseeable future.

Climate change (*Factor A* and *Factor E*) is a low- to medium-level stressor that is anticipated to result in shifts to the distribution of the subspecies' habitat and that may potentially affect gnatcatchers at the individual or population level into the foreseeable future. However, the impacts from climate change are not well understood and under some projections may increase habitat for the species as coastal sage scrub moves to higher elevations, though the impacts from climate change on its own are not fully understood. Therefore, while impacts of climate change are not fully understood, climate change is considered a low- to moderate-level threat that may affect the distribution of the subspecies and its habitat in the future.

New information we have received since the 2010 5-year review suggests that fragmentation (*Factor A* and *Factor E*) at small geographic scales is a threat of lower magnitude than was described at the time of listing. However, the effects of fragmentation are more significant at large geographic (landscape) scales than previously recognized for those coastal California gnatcatcher populations that have become widely separated due to urban development and other habitat losses or modifications (such as wildland fire). Therefore, we find that fragmentation still poses a threat to portions of the coastal California gnatcatcher subspecies, and we expect that these impacts will continue into the foreseeable future.

Furthermore, cumulative impacts from climate change and other factors such as vegetation type conversion and wildland fire have the potential to significantly alter habitat that currently supports the coastal California gnatcatcher. The wildland fire-type conversion feedback loop promotes the degradation and eventual loss of coastal California gnatcatcher habitat, particularly given the increase in fire frequency from the historical fire regime. Recent studies (such as Stavros *et al.* 2014) indicate that with climate change, fire frequency and intensity may continue to increase, which would in turn increase the wildland fire-type conversion feedback loop. The effects associated with climate change have the potential to further contribute to the vegetation type conversion process, though the exact impacts to coastal sage scrub habitat are unknown. Therefore, we find that cumulative impacts of multiple stressors are a threat to the coastal California gnatcatcher, and that this threat is likely to continue at the same level or increase into the foreseeable future.

Available regulatory mechanisms, such as the combined NCCP/HCP program and INRMPs on local military bases are providing important protections that help reduce the threats affecting the coastal California gnatcatcher and its habitat, such as urban development, vegetation type conversion, and fragmentation. Absent the provisions of the Act, some of these protections would no longer be in place. In Mexico, the listing of the *atwoodi* subspecies of the California gnatcatcher provides only a limited level of protection or conservation benefit, and comprehensive reserve areas for coastal California gnatcatcher habitat have not been established in northern Baja California. Therefore, absent the protections of the Act, existing regulatory mechanisms would provide substantially less protection from the threats currently acting on the subspecies.

Moreover, some of the threats faced by the coastal California gnatcatcher, such as wildland fire, vegetation type conversion, and habitat fragmentation, cannot be readily ameliorated through the application of regulatory mechanisms. Therefore, we conclude that the best available scientific and commercial information indicates that these threats are continuing to impact the subspecies and its habitat throughout its range, and that these impacts will continue into the foreseeable future. At this time, many threats are being reduced through existing regulatory mechanisms, and we expect that full implementation of regional NCCPs/HCPs will provide protection to much of the coastal sage scrub habitat that supports the coastal California gnatcatcher. However, many areas are not yet protected by existing plans and other plans are still in development.

Furthermore, many threats remain on the landscape that are not fully managed, and the best available scientific and commercial information indicates that these threats are likely to continue, such that the coastal California gnatcatcher is likely to become an endangered species within the foreseeable future throughout all its range. Because we have determined that the coastal California gnatcatcher is likely to become an endangered species throughout all its range within the foreseeable future, no portion of its range can be "significant" for purposes of the Act's definitions of "endangered species" and "threatened species." See the Service's final policy interpreting the phrase "significant portion of its range" (SPR) (79 FR 37578; July 1, 2014). Therefore, we find that the coastal California gnatcatcher continues to meet the definition of a threatened species under the Act, but that the threats are not severe enough at this time such that the species is in danger of extinction throughout its range. Therefore, we find that reclassification to an endangered species is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the coastal California gnatcatcher to our Carlsbad Fish and Wildlife Office (see **ADDRESSES**) whenever it becomes available. New information will help us monitor the subspecies and encourage additional conservation actions.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* in Docket Number FWS–R8–ES–2014–0058 and upon request from the Carlsbad Fish and Wildlife Office (see **ADDRESSES**).

Author(s)

The primary author(s) of this notice are the staff members of the Carlsbad Fish and Wildlife Office and Pacific Southwest Regional Office.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 15, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–20864 Filed 8–30–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 81, No. 169
Wednesday, August 31, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–NOP–16–0028; NOP–16–01]

National Organic Program: Notice of Draft Guidance on Treated Lumber

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of availability of draft guidance with request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing the availability of a draft guidance document intended for use by accredited certifying agents and organic producers. The draft guidance document is entitled: Treated Lumber (NOP 5036). This draft guidance document is intended to inform the public of the National Organic Program's (NOP) current thinking on this topic. The AMS invites interested parties to submit comments about these guidance provisions.

DATES: To ensure that NOP considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written comments on the draft guidance by October 31, 2016.

ADDRESSES: Submit written requests for hard copies of this draft guidance to Devon Pattillo, Agricultural Marketing Specialist, National Organic Program (NOP), USDA–AMS–NOP, 1400 Independence Ave. SW., Room 2646—So., Ag Stop 0268, Washington, DC 20250–0268. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

You may submit comments on this draft guidance document by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Devon Pattillo, Standards Division, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW., Room 2646—So., Ag Stop 0268, Washington, DC 20250–0268.

Instructions: Written comments responding to this request should be identified with the document number AMS–NOP–16–0028; NOP–16–01. You should clearly indicate your position and the reasons supporting your position. If you are suggesting changes to the draft guidance document, you should include recommended language changes, as appropriate, along with any relevant supporting documentation.

USDA intends to make available all comments, including names and addresses when provided, regardless of submission procedure used, on *www.regulations.gov* and at USDA, AMS, NOP, Room 2646-South building, 1400 Independence Ave. SW., Washington, DC, from 9 a.m. to noon and from 1 to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South building to view comments from the public to this notice are requested to make an appointment by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Devon Pattillo, Agricultural Marketing Specialist, National Organic Program (NOP), USDA–AMS–NOP, 1400 Independence Ave. SW., Room 2646—So., Ag Stop 0268, Washington, DC 20250–0268; Telephone: (202) 720–3252; Fax: (202) 260–9151; Email: *NOP.Guidance@ams.usda.gov;* or visit the NOP Web site at: *www.ams.usda.gov/nop.*

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document announced through this document was developed to clarify the requirements and limitations of the prohibition on treated lumber in organic production. USDA organic regulations (7 CFR part 205) prohibit use of lumber treated with arsenate or other non-allowed synthetic substances in contact with soil and livestock (7 CFR 205.206). Non-allowed synthetic substances include all synthetic substances that are not specifically included on the "National List" at 7 CFR 205.601 through 205–606.

The document provides guidance for certifying agents, organic producers, and other interested parties on compliance with 7 CFR 205.206(f), including:

- How lumber treated with prohibited substances affects a producer's timeline for obtaining certification;
- Where lumber treated with prohibited substances can and cannot be placed on organic farms, for new installations or replacement of existing lumber;
- How organic producers can prevent crops and livestock from contacting lumber treated with prohibited substances.

A notice of availability of final guidance on this topic will be issued upon its final approval. Once finalized, this guidance will be available in "The Program Handbook: Guidance and Instructions for Accredited Certifying Agents (ACAs) and Certified Operations". This Handbook provides those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the USDA organic regulations. The current edition of the Program Handbook is available online at *http://www.ams.usda.gov/rules-regulations/organic* or in print upon request.

II. Significance of Guidance

This draft guidance document is being issued in accordance with the Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (GGPs) (January 25, 2007, 72 FR 3432–3440).

The purpose of GGPs is to ensure that program guidance documents are developed with adequate public participation, are readily available to the public, and are not applied as binding requirements. This draft guidance represents NOP's current thinking on the topic. It does not create or confer any rights for, or on, any person and does not operate to bind the NOP or the public. Guidance documents are intended to provide a uniform method for operations to comply that can reduce the burden of developing their own methods and simplify audits and inspections. Alternative approaches that can demonstrate compliance with the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501–6522), and its implementing regulations are also acceptable. As with any alternative compliance approach, NOP strongly encourages industry to discuss alternative approaches with NOP before implementing them to avoid unnecessary or wasteful expenditures of resources and to ensure the proposed alternative approach complies with the Act and its implementing regulations.

III. Electronic Access

Persons with access to Internet may obtain the draft guidance at either NOP's Web site at *http://www.ams.usda.gov/rules-regulations/organic* or *http://www.regulations.gov.* Requests for hard copies of the draft guidance documents can be obtained by submitting a written request to the mailing address listed in the **ADDRESSES** section of this document.

Authority: 7 U.S.C. 6501–6522.

Dated: August 25, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–20808 Filed 8–30–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Beartooth Ranger District, Custer Gallatin National Forest; Carbon County, Montana; Greater Red Lodge Vegetation and Habitat Management Project

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare a supplemental environmental impact statement.

SUMMARY: The USDA Forest Service will prepare a Supplement to the Greater Red Lodge Vegetation and Habitat Management Project Final Environmental Impact Statement (EIS) to address the Forest Service's recent analysis and to determine whether a change in the Records of Decision are required.

DATES: The Forest Service will complete a final Supplemental EIS through preparing a draft Supplemental EIS by the fall of 2016. Once the Notice of Availability of the draft Supplemental EIS is published a required 45-day public comment period begins, 36 CFR 218.24(b)(5). At the conclusion of the 45-day period the Forest Service will (1) review and respond to comments and make necessary adjustments (based on comments) and prepare a final Supplemental EIS and (2) prepare a draft Record of Decision ("ROD") which will include a determination of whether changes are needed in the May 19, 2015 Records of Decision. Publication of the notice of opportunity to object to the final Supplemental EIS and draft ROD initiates the required 45-day objection period, 36 CFR 218.7(b), 218.26(a). Forest Service regulations then provide the Reviewing Officer 45 days to review the objections (with the discretion to extend the time up to 30 days), 36 CFR 218.26(b), after which the Agency must respond to any instructions by the Reviewing Officer prior to signing the ROD, 36 CFR 218.12. The Forest Service anticipates signing the final ROD in April 2017.

ADDRESSES: The line officer responsible for the decision is the Forest Supervisor for the Custer Gallatin National Forest, 10 East Babcock, Bozeman, MT 59715.

FOR FURTHER INFORMATION CONTACT: Until October 1, 2016, Mark Slacks, Team Leader, at (406) 255–1450. After October 1, 2016, Amy Waring, (406) 255–1451. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: On May 19, 2015, Forest Supervisor, Mary Erickson, approved two Records of Decision—one for the Greater Red Lodge Vegetation and Habitat Management Project (Project) and one for the Reconstruction of Nichols Creek Road. Both of these decisions were based on the Greater Red Lodge Vegetation and Habitat Management Project Final EIS. The Project encompasses approximately 21,871 acres in wildland urban interface (WUI) in Carbon County, Montana. The purposes of the project are to reduce high-intensity wildfire within the WUI, improve and maintain forest health, and improve water quality. Vegetation management proposed in the project area consists of both commercial and non-commercial vegetation fuels treatment on about 1,800 acres of land. In addition to vegetation management, the Project would decommission 3.9 miles of existing roadway. The RODs, final EIS, and supporting documents for the Project can be found at *http://www.fs.usda.gov/project/?project=41368&exp=detail.*

On Tuesday, June 28, 2016, the Forest Service suspended the Greater Red Lodge Area (GLRA) Stewardship Integrated Resource Timber Contract, Contract #02–200866 implementing the two RODs. No activity under the contract can occur until the suspension is lifted. The Project was suspended because the Forest Service recently discovered that the analysis of lynx critical habitat underestimated the number of acres of matrix habitat affected by the Project. At a minimum, the Forest Service will reanalyze the impacts of the Project on lynx critical habitat, in light of the corrected acres of matrix habitat. The Forest Service will not take any on-the-ground action to implement the Project until re-initiation of Endangered Species Act consultation is complete, a Supplemental EIS is issued, and the agency makes new decisions either affirming the current project or modifying the project based on the new analysis.

Nature of Decision To Be Made: The Forest Service will conduct a supplemental EIS analysis and issue a new ROD which will either affirm the existing agency decisions or will determine whether a new decision is necessary.

Scoping Process: Scoping is not required for supplements to environmental impacts statements, pursuant to 40 CFR 1509.9(c)(4). Scoping was conducted for the original EIS on June 14, 2012, and February 22, 2013. The supplement will be subject to notice and comment, as well as a predecisional administrative objection process (36 CFR part 218, subparts A and B).

Dated: August 24, 2016.

Mary C. Erickson,

Forest Supervisor.

[FR Doc. 2016–20920 Filed 8–30–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972 (5 U.S.C. App. II), the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1600 *et seq.*), the National Forest Management Act of 1976 (16 U.S.C. 1612), and the Federal Public Lands Recreation Enhancement Act (Pub. L. 108–447). Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's Web site at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Wednesday, September 21, 2016, at 1:00 p.m.

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Mystic Ranger District, 8221 South Highway 16, Rapid City, South Dakota.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Board Coordinator, by phone at 605–440–1409 or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide:

(1) Rushmore Connector Trail update;
(2) Proposed Land Exchange—Spearfish Canyon/Bismarck Lake;
(3) Teckla—Osage 230 kV Transmission Project update;
(4) Black Hills Resilient Landscapes Project update;
(5) BHNF Timber Program update (FY 16/FY 17);
(6) Forest Health Working Group update;
(7) Recreation Facilities Working Group update; and
(8) Non-motorized Trails/Over Snow Working Group update.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by September 12, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: August 25, 2016.

Mark Van Every,

Forest Supervisor.

[FR Doc. 2016–21008 Filed 8–30–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Manti-La Sal Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Manti-La Sal Resource Advisory Committee (RAC) will meet in Price, Utah. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://www.fs.usda.gov/main/pts/specialprojects/racweb.*

DATES: The meeting will be held on September 21, 2016, at 9:00 a.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Manti-La Sal National Forest Supervisor's Office, Conference Room, 599 West Price River Drive, Price, Utah. If you wish to attend via teleconference, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Manti-La Sal National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Duane Resare, Acting RAC Coordinator, by phone at 435–636–3535 or via email at *dresare@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to review and recommend projects authorized under Title II of the Act.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by September 1, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Duane Resare, Acting RAC Coordinator, Manti-La Sal National Forest Supervisor's Office, 599 West Price River Drive, Price, Utah 84501; by email to *dresare@fs.fed.us,* or via facsimile to 435–637–4940.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 12, 2016.

Brian Mark Pentecost,

Forest Supervisor.

[FR Doc. 2016–20948 Filed 8–30–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request Revision and Extension of a Currently Approved Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intent of the National Agricultural Statistics Service (NASS) to request revision and extension of a currently approved information collection to comply with a

mandate in the 2014 Farm Bill. (. . . the Secretary of Agriculture should recognize the threat feral swine pose to the domestic swine population and the entire agriculture industry . . .).

DATES: Comments on this notice must be received by October 31, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–0256, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *Efax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: R. Renee Picanso, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Feral Swine Survey.

OMB Control Number: 0535–0256.

Type of Request: Intent to Seek Approval to Revise and Extend an Information Collection for three Years.

Abstract: On April 2, 2014 the Undersecretary for USDA's Marketing and Regulatory Programs, Edward Avalos announced that the USDA was kicking off a national effort to reduce the devastating damage caused by feral swine. In 2015 the benchmark survey was conducted in 11 States (Alabama, Arkansas, California, Florida, Georgia, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, and Texas) to measure the amount of damage, feral hogs caused to crops in these states. The target population within these states consisted of farm operations who have historically produced one or more of the following crops: Corn, soybeans, wheat, rice, peanuts, or sorghum (Texas only). The results of this benchmark survey shows that in the 11 surveyed States, there was damage to an estimated $190 million in crops for the six target crops. The published findings from this benchmark survey can be found at *http://www.sciencedirect.com/science/article/pii/S0261219416301557.*

In 2017, this survey will be conducted in the following 13 States: Alabama, Arkansas, California, Florida, Georgia, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas, to measure the damage to livestock that is associated with the presence of feral swine. These States have high feral swine densities and a significant presence of cattle, hogs, sheep and/or goats. The eradication of feral swine is a high priority of the Secretary and is authorized by the Animal Health Protection Act (Title 7 U.S.C. 8301 *et seq.*) and the 2014 Farmbill.

The $20 million program aims to help states deal with a rapidly expanding population of invasive wild swine. "Feral swine are one of the most destructive invaders a state can have," said Undersecretary Avalos. "They have expanded their range from 17 to 39 states in the last 30 years and cause damage to crops, kill young livestock, destroy property, harm natural resources, and carry diseases that threaten other animals as well as people and water supplies. It's critical that we act now to begin appropriate management of this costly problem."

On Feb 3, 1999, Executive Order 13112 was signed by President Clinton establishing the National Invasive Species Council. The Executive Order requires that a Council of Departments dealing with invasive species be created. Currently there are 13 Departments and Agencies on the Council. (*Executive Order 13112 of February 3, 1999—Invasive Species* ***Federal Register****: Feb 8, 1999 (Volume 64, Number 25)).*

The Animal and Plant Health Inspection Service (APHIS), Wildlife Services' (WS) National Wildlife Research Center (NWRC) is the only Federal research organization devoted exclusively to resolving conflicts between people and wildlife through the development of effective, selective, and socially responsible methods, tools, and techniques. As increased urbanization leads to a loss of traditional wildlife habitat, the potential for conflicts between people and wildlife increases. Such conflicts can take many forms, including property and natural resource damage, human health and safety concerns, and disease transmission among wildlife, livestock, and humans.

The high reproductive rate and adaptability of feral swine has resulted in populations that have dramatically increased in size and distribution. This invasive animal now occurs across much of the United States where it causes a range of agricultural and environmental damage through depredation, rooting, and wallowing activities. Furthermore, feral swine compete with native wildlife and livestock for habitats, are carriers of exotic and endemic diseases, and transmit parasites to livestock and humans. Feral swine are considered a major emerging threat to American agriculture (Seward et al. 2004). Recent data show that the proportions of U.S. counties with agricultural production that also have feral swine present are increasing.

This initial livestock survey will be used to create a benchmark for the following objectives:

1. Describe the monetary loss for livestock caused by feral swine to producers of cattle, hogs, sheep and/or goats in each of the surveyed states due to predation by feral swine.
2. Describe the monetary loss for livestock caused by feral swine to producers of cattle, hogs, sheep and/or goats in each of the surveyed states due to diseases carried by feral swine.
3. Describe the monetary costs for any medical treatments on livestock due to the presence of, or contact with, feral swine.
4. Describe the monetary loss to livestock farmers caused by feral swine to the total crops produced on farms in each of the surveyed states.
5. Describe the monetary loss to property caused by feral swine for producers of cattle, hogs, sheep, and/or goats in each of the surveyed states.
6. Describe feral swine control costs incurred by producers of cattle, hogs, sheep, and/or goats in each of the surveyed states. Variables that will be measured include hunting, trapping, use of fencing, or the use of repellents. No data will be collected on the use of chemical or physical contraception usage.
7. Describe the total net income to producers of cattle, hogs, sheep, and/or goats in each of the surveyed states for allowing the hunting or trapping of feral swine on their operations.

Based on the results of this survey, Wildlife Service plans to publish state level data if possible. Also, there may be a follow-up survey to measure the effectiveness of control measures implemented by Wildlife Services. This follow-up survey will also be contingent upon availability of funding.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 Public Law 104–13 (44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, "Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)," **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Reporting burden for this collection of information is estimated to average 45 minutes per response. This was determined by our Survey Methodologists, who compared the length and difficulty of the questions with similar surveys. They also took into account the projected number of farmers who will skip some sections of the questionnaire due to the presence or absence of damage due to feral swine. Burden is based on an estimated minimum response rate of 80%. On similar types of surveys and through the use of a mail questionnaire and telephone follow-up to non-respondents NASS has been able to contact and collect some data from approximately 80% of the target sample. After removing the out of business operations and those with no items of interest we hope to have at least a 65 to 70% usable response rate.

NASS will be utilizing several pieces of publicity and informational materials to encourage respondents to participate in this important survey. NASS will conduct the survey initially by mail with phone follow-up for non-response.

Respondents: Farm Operators.

Estimated Annual Number of Respondents: 12,000.

Estimated Total Annual Burden on Respondents: 9,300 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, technological or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, August 22, 2016.

R. Renee Picanso,

Associate Administrator.

[FR Doc. 2016–20900 Filed 8–30–16; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Advisory Committee on Agriculture Statistics

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice of the Charter renewal for the Advisory Committee on Agriculture Statistics.

SUMMARY: The U.S. Department of Agriculture (USDA) is seeking renewal of the 2-year charter for its discretionary committee, the Advisory Committee on Agriculture Statistics. Effective October 1, 1996, responsibility for the census of agriculture program was transferred to the National Agricultural Statistics Service (NASS) at USDA from the Bureau of the Census, U.S. Department of Commerce. Effective February 2, 1997, NASS also received the transferred program positions and staff from the Bureau of the Census, U.S. Department of Commerce. Responsibility for the Advisory Committee on Agriculture Statistics, which is a discretionary committee and was established by agency authority, was transferred, along with its allocated slot, to USDA with the census of agriculture program.

Authority: The Advisory Committee on Agriculture Statistics was originally established by the Secretary of Commerce on July 16, 1962. The Committee is also established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.2.

FOR FURTHER INFORMATION CONTACT: Hubert Hamer, Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–2707, or email *HQOA@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of the Committee is to advise the Secretary on the conduct of the periodic censuses and surveys of agriculture, other related surveys, and the types of agricultural information to obtain from respondents. The committee also prepares recommendations regarding the content of agriculture reports, and presents the views and needs for data of major suppliers and users of agriculture statistics. The committee draws on the experience and expertise of its members to form a collective judgment concerning agriculture data collected and the statistics issued by the National Agricultural Statistics Service (NASS).

Description of Duties: The duties of the Committee are solely advisory in nature. The Committee makes recommendations to the Secretary of Agriculture with regard to the agricultural statistics program of NASS, and such other matters as it may deem advisable, or which the Secretary of Agriculture, Under Secretary for Research, Education, and Economics, or the Administrator of NASS may request.

Agency or Official to Whom the Committee Reports: The Committee reports to the Secretary of Agriculture through the Under Secretary for Research, Education, and Economics.

Committee Membership: The Secretary of Agriculture will appoint the membership of the Committee. Furthermore, members will serve for two-year terms, and can serve no more than three consecutive terms. Membership will consist of 20 individuals with diverse capabilities distinguished by their broad range of knowledge and interest in, though not limited to, agricultural economics, rural sociology, farm policy analysis, and agricultural education. Members will also be drawn from representatives of state and local governments; agriculture-related industry and trade or marketing associations; major national farm organizations; and producer organizations. A representative from the Bureau of the Census, U.S. Department of Commerce, and a representative from the Economic Research Service, USDA, shall serve as ex officio members of the Committee.

This Committee will be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. Steps will be taken to encourage fresh points of view, such as establishing staggered membership terms and limiting the number of renewed memberships.

Equal opportunity practices in accordance with USDA policies will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDA, membership will include to the extent possible, individuals with demonstrated ability to represent the needs of all racial and ethnic groups, women and men, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

Ethics Statement: To maintain the highest levels of honesty, integrity and ethical conduct, no Committee or subcommittee member shall participate in any "specific party matters" (*i.e.,* matters are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for Committee or Subcommittee members to immediately disclose to the Designated Federal Officer (DFO) any specific party matter in which the member's immediate family, relatives, business partners or employer would be directly seeking to financially benefit from the Committee's recommendations.

All members will receive ethics training to identify and avoid any actions that would cause the public to question the integrity of the Committee's advice and recommendations. Members who are appointed as "Representatives" are not subject to Federal ethics laws because such appointment allows them to represent the point(s) of view of a particular group, business sector or segment of the public.

Members appointed as "Special Government Employees" (SGEs) are considered intermittent Federal employees and are subject to Federal ethics laws. SGE's are appointed due to their personal knowledge, academic scholarship, background or expertise. No SGE may participate in any activity in which the member has a prohibited financial interest. Appointees who are SGEs are required to complete and submit a Confidential Financial Disclosure Report (OGE–450 form) and, upon request, USDA will assist SGEs in preparing these financial reports. To ensure the highest level of compliance with applicable ethical standards USDA will provide ethics training to SGEs on an annual basis. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

Recordkeeping: The records of this Committee, formally and informally established subcommittees, or other subgroups of the committee, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Information about this Committee is available online at:*https://www.nass.usda.gov/About_NASS/Advisory_Committee_on_Agriculture_Statistics/index.php.*

Signed at Washington, DC, August 22, 2016.

Renee Picanso,

Associate Administrator.

[FR Doc. 2016–20899 Filed 8–30–16; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the South Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting; postponement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that an emergency telephonic meeting of the South Dakota Advisory Committee to the Commission was convened at 2 p.m. on Thursday, August 18, 2016. The purpose of the emergency meeting was to discuss and vote to postpone briefing meeting on the "Subtle Effects of Racism in South Dakota," scheduled for Thursday, August 25, 2016 in Aberdeen, SD. The reason for postponing the August 25 meeting is due to a police shooting in Aberdeen that is under state investigation.

DATES: The meeting scheduled for August 25, 2016 is postponed. A new date has not been set.

FOR FURTHER INFORMATION CONTACT: Malee Craft at *mcraft@usccr.gov,* or 303–866–1040.

SUPPLEMENTARY INFORMATION: Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=274* and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Commission's Rocky Mountain Regional Office, as they become available, both before and after the meeting.

Additional notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the briefing meeting of the South Dakota Advisory Committee to the Commission scheduled for 1:00 p.m. on Thursday, August 25, 2016, in the Community Room on the 1st Floor of the Aberdeen Public Safety Building, 114 2nd Avenue SE., Aberdeen, SD 57401, HAS BEEN POSTPONED by a vote of the SD State Advisory Committee. The vote to postpone was due to a recent critical incident in the Aberdeen community. A subsequent meeting date has not been scheduled.

Exceptional Circumstance: Pursuant to the Federal Advisory Committee Management Regulations (41 CFR 102–3.150), the notice for this meeting is given less than 15 calendar days prior to the meeting due to exceptional circumstances. Given the exceptional urgency of the events, the agency and advisory committee deemed it important for the advisory committee to meet on the date given to discuss postponement of the August 25 briefing.

Dated: August 24, 2016.

Brian Walch,

Director, Communications and Public Engagement.

[FR Doc. 2016–20969 Filed 8–30–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Survey of Income and Program Participation (SIPP).

OMB Control Number: 0607–0977.

Form Number(s):

SIPP–105(L1)(2016) (Advance Letter—No Incentive)
SIPP–105(L3)(2016) (Advance Letter—$40 Incentive)
SIPP–PIN–2016 (2016 PIN Letter)
SIPP–101 (Factsheet)
SIPP–106(L1)(2016) (Thank You Letter—No Incentive)
SIPP–106(L2)(2016) (Thank You Letter—$40 Incentive)

Type of Request: Renewal of OMB Approval.

Number of Respondents: 64,050.

Average Hours per Response: 0.67.

Burden Hours: 42,700.

Needs and Uses: The SIPP is a household-based survey designed as continuous series of national panels. The SIPP represents a source of information for a wide variety of topics and allows the integration of information for separate topics to form a single, unified database allowing for the examination of the interaction between tax, transfer, and other government and private policies. Government domestic policy formulators depend heavily upon SIPP information concerning the distribution of income received either directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on that distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population, which the SIPP has provided on a continuing basis since 1983. The SIPP has measured levels of economic well-being and permitted measurement of changes in these levels over time.

The 2014 SIPP interview includes a portion conducted using an Event History Calendar (EHC) that facilitates the collection of dates of events and spells of coverage. The EHC assists the respondent's ability to recall events accurately over the one year reference period and provides increased data quality and inter-topic consistency for dates reported by respondents. The EHC is intended to help respondents recall information in a more natural "autobiographical" manner by using life events as triggers to recall other economic events. The EHC was previously used in the 2010–2013 SIPP–EHC field tests in addition to 2014 Panel Waves 1 and 2. The 2014 Panel SIPP design does not contain freestanding topical modules; however, a portion of traditional SIPP topical module content is integrated into the 2014 SIPP Panel interview. Examples of this content include questions on medical expenses, child care, retirement and pension plan coverage, marital history, adult and child well-being, and others.

Affected Public: Respondents, researchers, policymakers.

Frequency: The 2014 SIPP Panel is an annual survey that runs for four years consecutively.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 141 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 25, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–20902 Filed 8–30–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RINS 0648–XZ51, 0648–XA524, 0648–XA756, 0648–XD824, 0648–XE041, 0648–XE580, 0648–XE599, and 0648–XE622

Marine Mammals and Endangered Species; File Nos. 15543–06, 15488–01, 15537–02, 18890, 19091, 19116, 19638, 20283

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits and amendments.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities:

Permit No. 15543–06: Randy Wells, Ph.D., Sarasota Dolphin Research Program, c/o Mote Marine Laboratory, 1600 Ken Thompson Parkway, Sarasota, FL 34236;

Permit No. 15488–01: Georgia Department of Natural Resources (GADNR), Wildlife Resources Division, 2070 U.S. Hwy 278 SE., Social Circle, GA 30025 (Dan Forster, Responsible Party);

Permit No. 15537–02: Institute for Marine Mammal Studies (IMMS), P.O. Box 207, Gulfport, MS 39502 (Moby Solangi, Ph.D., Responsible Party);

Permit No. 18890: Alaska Department of Fish and Game (ADFG), 1255 West 8th Street, Juneau, Alaska, 99811–5526 (Robert Small, Ph.D., Responsible Party);

Permit No. 19091: NMFS Southwest Fisheries Science Center (SWFSC), 8901 La Jolla Shore Dr., La Jolla, CA 92037, [Lisa Ballance, Ph.D., Responsible Party];

Permit No. 19116: Brandon Southall, Ph.D., Southall Environmental Services Inc., 9099 Soquel Drive, Suite 8, Aptos, CA 95003;

Permit No. 19638: Paul Ponganis, Ph.D., University of California at San Diego, La Jolla, CA, 92093; and

Permit No. 20283: Demian Chapman, Ph.D., School of Marine and Atmospheric Science, Stony Brook University, Stony Brook, NY 11794.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore (Permit Nos. 15537–02, 20283), Amy Sloan (Permit Nos. 15537–02, 15543–06, 18890, 19638), Carrie Hubard (Permit No. 15488–01), Amy Hapeman (Permit No. 19091), and Sara Young (Permit Nos. 19116 and 19638), (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** that requests for a permit had been submitted by the above-named applicants, as applicable. The requested permits have been issued under the following authorities, as applicable: The Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 15543 (Dr. Wells) was issued on May 26, 2011 (76 FR 32144, June 3, 2011), authorizing research on bottlenose dolphins (*Tursiops truncatus*) in Florida including photo-identification, behavioral studies, remote biopsy sampling, and captures for health assessments. The purpose of the research is to study population structure and dynamics, life history, social structure, genetic structure, health and physiology, and human interactions including assessments of oil spill impacts. The permit was amended on four occasions to add minor changes to protocols, and on one occasion via a major amendment (80 FR 23258, April 27, 2015) to expand the study area to include Alabama and Louisiana, and to add studies on Atlantic spotted dolphins (*Stenella frontalis*). The issued minor amendment (No. 15543–06) extends the duration of the permit through June 1, 2017, and adds the use of an alternative stable isotope and administration technique for physiology studies, but otherwise does not change any other terms or conditions of the permit.

Permit No. 15488 (GADNR) issued on June 24, 2011 (75 FR 75458, December

3, 2010), authorizes research on North Atlantic right whales (*Eubalaena glacialis*) off the coast of Georgia, Florida, and South Carolina. Activities include aerial surveys, vessel surveys, photo-identification, biopsy sampling, and behavioral observations. The purpose of the research is to monitor population status, demographics, habitat and anthropogenic impacts. The issued minor amendment (No. 15488–01) extends the duration of the permit through June 30, 2017, but does not change any other terms or conditions of the permit.

Permit No. 15537 (IMMS) was issued on October 5, 2011 (76 FR 63286, October 12, 2011), authorizing the acquisition of up to eight stranded, releasable California sea lions (*Zalophus californianus*) from the NMFS Marine Mammal Health and Stranding Response Program for the purposes of public display. Permit No. 15537 was amended on May 2, 2016 (81 FR 33217, May 25, 2016), in response to a Court-ordered remand of the permit to NMFS for reconsideration. *IMMS* v. *NMFS, No. 1:11CV318–LG–JMR* (S.D.Miss. 2014). Permit Condition B.3 was removed, Permit Condition B.2 was amended and the permit was extended for one year. The issued permit amendment (No. 15537–02) further extends the duration of permit through December 31, 2018, but does not change any other terms or conditions of the permit.

Permit No. 18890 (ADF&G; 80 FR 15992, March 26, 2015) authorizes research on beluga (*Delphinapterus leucas*), bowhead (*Balaena mysticetus*), gray, and humpback whales in Alaska including photo-identification, biopsy sampling, and tagging (large whales and belugas) and aerial surveys and captures for health assessments (belugas, excluding the Cook Inlet Distinct Population Segment). Research studies include population abundance (beluga), stock structure (bowhead, gray, humpback, and beluga), feeding areas and other important habitats (all species), migration routes (all species), behavior relative to human disturbance (all species), and to genetically identify individuals in order to determine survival and calving intervals (belugas). Ice seals may be incidentally captured or harassed during research. Biological samples may be imported or exported for analysis. The permit is valid for five years from the date of issuance.

Permit No. 19091 (SWFSC; 80 FR 45196, July 29, 2015) authorizes research on over 55 species of marine mammals and five species of sea turtles in all oceans of the world, with special focus on the eastern Pacific Ocean. The purpose of this research is to determine the abundance, distribution, movement patterns, dive behavior, demography and stock structure, and to monitor trends in recruitment of pinnipeds, cetaceans, and sea turtles in U.S. territorial and international waters. Researchers may conduct ground, vessel, and aerial surveys for observation, photogrammetry, photo-identification, biological sampling, and tagging animals. A request to use fully implantable satellite tags for cetaceans was denied. Researchers also may salvage and receive/import/export specimens and biological samples of these species. The permit is valid for five years from the date of issuance.

Permit No. 19116 (Dr. Southall; 81 FR 29847, May 13, 2016) authorizes research involving studies of sound production, diving and other behavior, and responses to sound of sixteen species of marine mammals, including endangered species. This study involves close approaches, attachment of tags, and sound exposure. Small fragments of sloughed skin, which often remain attached to retrieved tags, would be used for genetic analyses. Target species include beaked whales and other odontocetes, key baleen whales, and pinniped species for whom such data have not been previously obtained; other marine species may be incidentally harassed. The permit is valid for five years from the date of issuance.

Permit No. 19638 (Dr. Ponganis; 81 FR 29846, May 13, 2016) authorizes research to determine the role of blood oxygen store depletion in the dive behavior and foraging ecology of California sea lions on San Nicolas Island, California. Lactating females would be captured, flipper tagged, anesthetized, and equipped with a venous or arterial blood oxygen recorder, a velocity-acceleration-depth recorder, kinematic recorders, intravascular lactate sensor, or intravascular thermistor probe during foraging trips to sea. Animals would be recaptured after the foraging trip to remove the recorders. The pups of the females would also be captured and marked for ID purposes. Other pinnipeds may be incidentally harassed. The permit is valid for five years from the date of issuance.

Permit No. 20283 (Dr. Chapman; 81 FR 33212, May 25, 2016) authorizes the import of scalloped hammerhead shark (*Sphyrna lewini*) samples obtained from the Hong Kong fish market in order to assess global trade of shark fins through genetic analysis. Samples from up to 200 individuals would be imported to the Florida International University for analysis. The permit is valid for two years from the date of issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement, with the exception of File No. 19116.

For File No. 19116, an environmental assessment (EA) was prepared analyzing the effects of the permitted activities on the human environment in compliance with NEPA. Based on the analyses in the EA, NMFS determined that issuance of the permit would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact, signed on July 8, 2016.

As required by the ESA, as applicable, issuance of these permits were based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: August 25, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–20941 Filed 8–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

United States Global Change Research Program (USGCRP)

AGENCY: National Oceanic and Atmospheric Administration (NOAA) United States Global Change Research Program (USGCRP).

ACTION: Request for public nominations.

Context: The U.S. Global Change Research Program (USGCRP) is mandated under the Global Change Research Act (GCRA) of 1990 to conduct a quadrennial National Climate Assessment (NCA). Under its current decadal strategic plan (*http://go.usa.gov/3qGU4*) USGCRP is building sustained assessment capacity. The sustained assessment supports the Nation's ability to understand, anticipates, and responds to risks and potential impacts brought about by global environmental change, namely the human-caused buildup of greenhouse gases in our atmosphere that is causing climate change.

The last NCA from 2014 (NCA3: *http://nca2014.globalchange.gov*) and the process to develop it provided a foundation for subsequent activities and reports.

Comments have been received through a request for information on the draft, annotated outline for the Fourth National Climate Assessment (NCA4) *https://www.federalregister.gov/articles/2016/07/05/2016-15807/public-comment-on-an-annotated-outline-for-the-fourth-national-climate-assessment.* Informed by these comments, a revised outline, including a chapter list, is provided below and available online *https://www.globalchange.gov/notices.* Sectoral and response chapters will be coordinated and led by federal agencies. Regional chapters will be coordinated and led by non-federal regional chapter leads, who in turn will collaborate with federal coordinating lead authors.

For each regional chapter, a non-federal regional chapter lead must be nominated through this call for nominations and then selected by the Federal NCA4 Steering Committee. This non-federal regional chapter lead will then, with input and guidance from the Federal NCA4 Steering Committee, select federal and non-federal chapter authors and technical contributors to establish regional author teams. A federal coordinating lead author will also work with each regional chapter lead as a liaison between the regional chapter lead and federal agencies. Federal coordinating lead authors will provide technical editorial oversight of report content.

The regions that NCA4 will cover are the Northeast, Southeast and the Caribbean, Midwest, Northern Plains, Southern Plains, Southwest, Northwest, Alaska, and Hawai'i and Pacific Islands. See below in the appendix for the sectors, responses, and cross-cutting topics that will be covered.

In addition, this request presents an opportunity to submit scientific/technical information to inform the assessment. These technical inputs on sectoral, regional, and response information and cross-cutting topics will serve as part of the foundation for NCA4.

SUMMARY: NOAA, on behalf of USGCRP, is soliciting nominations for regional chapter leads, chapter authors, technical contributors and technical/scientific information for the Fourth National Climate Assessment (NCA4). Refer to the NCA4 Annotated Outline (accessible below in the Appendix and via *www.globalchange.gov/notices*) for further information on the scope, topics, and overarching themes for the report, as well as roles and responsibilities for nominated leads, authors, and contributors.

The report will adhere to the Information Quality Act requirements (*http://www.cio.noaa.gov/services_programs/info_quality.html*) for quality, transparency, and accessibility as appropriate for a Highly Influential Scientific Assessment (HISA).

DATES: Nominations should be submitted via the web address specified below (See **ADDRESSES**) and must be received within 30 days of publication of this Notice.

ADDRESSES: Nominations for regional chapter leads, chapter authors, and technical contributors must be submitted electronically via a web form accessible via *https://www.globalchange.gov/notices.* Nominees will identify their areas of expertise based on NCA4's sectoral and response topics. A short CV/resume of no more than 4 pages must be included. Technical inputs should also be submitted electronically via web form accessible from *https://www.globalchange.gov/notices.*

Instructions: Response to this notice is voluntary. Responses to this notice may be used by the government for program planning on a non-attribution basis. NOAA therefore requests that no business proprietary information or copyrighted information be submitted in response to this notice. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Emily Therese Cloyd, (202) 223–6262, *ecloyd@usgcrp.gov,* U.S. Global Change Research Program.

SUPPLEMENTARY INFORMATION: Background information, additional details, and instructions for submitting nominations and technical inputs can be found at *www.globalchange.gov/notices.* For the responsibilities and expectations of different kinds of authors and contributors, please see: *www.globalchange.gov/notices.* For more information about the NCA and access to previous NCA reports and activities, please see *http://assessment.globalchange.gov.*

Call for Nominations for Regional Chapter Leads, Chapter Authors and Technical Contributors, this notice seeks nominations for regional chapter leads, chapter authors, and technical contributors to NCA4 with pertinent subject matter expertise and scientific background. Potential nominees should be accomplished scholarly writers and have demonstrated scientific and technical expertise and academic proficiency in at least one of the regions, sectors, response, or climate science topics outlined in the NCA4 Annotated Outline, (described below in the Appendix and accessible via *https://www.globalchange.gov/notices*). Submissions must show that nominees have demonstrated technical backgrounds such that they could contribute to the development of a robust scientific, technical assessment as subject matter experts in one or more of the topics listed in the outline.

Responses to this request for nominations for regional chapter leads, chapter authors, and technical contributors must be submitted within 30 days of the publication of this notice. Users can access the nominations form via *www.globalchange.gov/notices.* Interested persons may nominate themselves or third parties, and may nominate more than one person. Each nomination must include: (1) The nominee's full name, title, institutional affiliation, and contact information; (2) the nominee's area(s) of expertise; (3) a short description of his/her qualifications relative to contributing to the report; and (4) a current resume/CV [maximum length four (4) pages].

Nominations will be reviewed and selected by the Federal NCA4 Steering Committee. Non-federal nominees may be selected and requested to serve as regional chapter leads, and other federal and non-federal nominees may be invited to participate as chapter authors or technical contributors to NCA4. Those selected as regional chapter leads will be informed no later than six weeks after the close of the nominations window. Those not selected as non-federal chapter leads may have their information passed on to Federal agencies or non-federal chapter leads for further consideration as chapter authors or technical contributors.

Call for Relevant Scientific Information to Inform NCA4

Interested parties are invited to assist in contributing, collecting, and refining the scientific information base for NCA4. To do so, parties are asked to submit recent, relevant scientific and/or technical research studies including observed, modeled and/or projected climate science information that have been peer reviewed and published or accepted for publication in scientific journals and/or government reports. For some elements of NCA4 (such as adaptation issues), relevant literature may not always be in the scientific peer-reviewed literature. These other types of literature (*e.g.,* reports that are produced by the non-profit and business communities) may still be submitted as input. All information used in the report is expected to comply with NOAA Information Quality Act standards.

Please refer to the outline (See Appendix below for topics covered in NCA4) to target your submissions. We especially encourage submissions of regional information and information for such topics as case studies, economic valuation, and cross-cutting sectoral research. All scientific literature submitted in response to this call for information must be received by January 15, 2017. For best consideration, please submit by November 1, 2016.

Submissions must be uploaded electronically via the link provided on *http://www.globalchange.gov/notices.*

Appendix: NCA4 Updated Outline

I: Overview
II: Our Changing Climate
III: National Analyses/Sectoral Chapters
  Water
  Energy
  Ecosystems, Ecosystem Services, and Biodiversity
  Oceans and Marine Resources
  Coastal Effects
  Agriculture and Food Production
  Forests
  Land Cover and Land Use Change
  Transportation
  Built Environment, Urban Systems, and Cities
  Human Health
  Air Quality
  Energy, Water, Land Nexus
  Tribal and Indigenous Communities
  North American and Other International Effects
IV: Regional Analyses
  Northeast
  Southeast and Caribbean
  Midwest
  Northern Plains
  Southern Plains
  Northwest
  Southwest
  Alaska
  Hawai'i and Pacific Islands
V: Response
  Near-Term Adaptation Needs and Increased Resiliency
  Mitigation: Avoiding and Reducing Long-Term Risks

Dated: Thursday, August 18, 2016.

Dan Barrie, *Program Manager, Assessments Program, NOAA Climate Program Office*

Published on TBD.

Dated: August 25, 2016.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–20982 Filed 8–30–16; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, August 31, 2016, 10 a.m.–11.a.m.*

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

Matter To Be Considered

Decisional Matter: Fall 2016 Regulatory Agenda

A live webcast of the Meeting can be viewed at *www.cpsc.gov/webcast.*

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

* The Commission unanimously determined by recorded vote that Agency business requires calling the meeting without seven calendar days advance public notice.

Dated: August 29, 2016.

Todd A. Stevenson,

Secretary.

[FR Doc. 2016–21076 Filed 8–29–16; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Intent To Grant Exclusive Patent License to Fox Materials Consulting, LLC; Colorado Springs, CO

AGENCY: Department of the Army, DoD.

ACTION: Notice of intent.

SUMMARY: In compliance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i), the Department of the Army hereby gives notice of its intent to grant to Fox Materials Consulting, LLC; a corporation having its principle place of business at 7145 Baker Rd., Colorado Springs, CO 80908, an exclusive license in the field of semiconductor applications that use nonvolatile switches and relays relative to the following:

- "Ferroelectric Mechanical Memory and Method", US Patent No.: 9,385,306, Filing Date March 12, 2015, Issue Date July 5, 2016.
- "Ferroelectric Mechanical Memory Based on Remanant Displacement and Method", US Patent Application No.: 15/131,881, Filing Date April 18, 2016.

DATES: Written objections must be filed not later than 15 days following publication of this announcement.

ADDRESSES: Send written objections to U.S. Army Research Laboratory Technology Transfer and Outreach Office, RDRL–DPT/Thomas Mulkern, Building 321, Room 110, Aberdeen Proving Ground, MD 21005–5425.

FOR FURTHER INFORMATION CONTACT: Thomas Mulkern, (410) 278–0889, email: *ORTA@arl.army.mil.*

SUPPLEMENTARY INFORMATION: The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the U.S. Army Research Laboratory receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by the U.S. Army Research Laboratory within fifteen (15) days from the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2016–20922 Filed 8–30–16; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF EDUCATION

Funding Down the State and Partnership Grant Slates From Fiscal Year (FY) 2014; Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP)

[Catalog of Financial Domestic Assistance (CFDA) Numbers: 84.334S and 84.334A]

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of intent to fund down the State and partnership grant slates from FY 2014.

SUMMARY: The Secretary intends to use grant slates developed in FY 2014 for the GEAR UP Program authorized by Section 404A of the Higher Education Act of 1965, as amended (HEA), to make new grant awards in FY 2016. The Secretary takes this action because a number of high-quality applications remain on the FY 2014 State and partnership grant slates and limited funding is available for new grant awards in FY 2016. We expect to use an estimated $20,000,000 for new awards in FY 2016.

FOR FURTHER INFORMATION CONTACT: Karmon Simms-Coates, U.S. Department of Education, 400 Maryland Avenue SW., Room 5W250, Washington, DC 20202. Telephone: (202) 453–7917 or by email: *karmon.simms-coates@ed.gov*.

If you use a telecommunications device for the deaf or a text telephone, call the Federal Relay Service, toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2014, the Department of Education published two notices in the **Federal Register** (79 FR 32241 (State Grants) and 79 FR 32249 (Partnership Grants)) inviting applications for FY 2014 State and partnership new awards under the GEAR UP Program.

In response to the notices, we received a number of high-quality applications. Many applications that received high scores by peer reviewers were not selected for funding.

To conserve funding that would have been required for a peer review of new grant applications submitted under this program and instead use those limited funds to support grant activities, the FY 2015 GEAR UP grantees were selected from the State and partnership slates developed during the FY 2014 competition using the priority, selection criteria, and application requirements referenced in the June 2014 notice. A number of high-quality applications from the 2014 competition were not funded in 2014 or 2015. We will select new grantees in FY 2016 from the existing State and partnership slates developed in FY 2014 for the same reasons and in the same manner as we did in FY 2015.

Program Authority: 20 U.S.C. 1070a–21–1070a–28.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at this site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 26, 2016.

Lynn B. Mahaffie,

Deputy Assistant Secretary for Policy, Planning and Innovation, Delegated the Duties of the Assistant Secretary for Postsecondary Education.

[FR Doc. 2016–21006 Filed 8–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0095]

Agency Information Collection Activities; Comment Request; Foreign Schools Eligibility Criteria Apply To Participate in Title IV HEA Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 31, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0095. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Foreign Schools Eligibility Criteria Apply to Participate in Title IV HEA Programs.

OMB Control Number: 1845–0105.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 4,135.

Total Estimated Number of Annual Burden Hours: 398.

Abstract: The information in 34 CFR 600.54, 600.55, 600.56 and 600.57 is used by the Department during the initial review for eligibility certification, recertification and annual evaluations. These regulations help ensure that all foreign institutions participating in the Title IV, Higher Education Act (HEA) Programs are meeting the minimum participation standards.

Dated: August 26, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–20990 Filed 8–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0094]

Agency Information Collection Activities; Comment Request; Application for Approval To Participate in Federal Student Aid Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 31, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0094. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Veronica Pickett, 202–377–4232.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Approval to Participate in Federal Student Aid Programs.

OMB Control Number: 1845–0012.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 7,286.

Total Estimated Number of Annual Burden Hours: 24,352.

Abstract: Section 487(c) of the Higher Education Act of 1965, as amended (HEA) requires that the Secretary of Education prescribe regulations to ensure that any funds postsecondary institutions receive under the HEA are used solely for the purposes specified in, and in accordance with, the provision of the applicable programs. The Institutional Eligibility regulations govern the initial and continuing eligibility of postsecondary educational institutions participating in the student financial assistance program authorized by Title IV of the HEA. An institution must use this Application to apply for approval to be determined to be eligible and if the institution wishes, to participate; to expand its eligibility; or to continue to participate in the Title IV programs. An institution must also use the application to report certain required data as part of its recordkeeping requirements contained in the regulations under 34 CFR part 600 (Institutional Eligibility under the HEA). The Department uses the information reported on the Application in its determination of whether an institution meets the statutory and regulatory requirements.

Dated: August 26, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–20938 Filed 8–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Catalog of Federal Domestic Assistance (CFDA) Number: 84.215N]

Extension of the Application Deadline Date for the Fiscal Year 2016; Promise Neighborhoods Program Grant Application

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

SUMMARY: The Assistant Deputy Secretary for Innovation and Improvement extends, for certain prospective eligible applicants described elsewhere in this notice, the deadline date for transmittal of applications for new awards for fiscal year (FY) 2016 under the Promise Neighborhoods program. The Assistant Deputy Secretary takes this action to allow more time for the preparation and submission of applications by prospective eligible applicants in Louisiana affected by the severe storms and flooding that began in that State on August 11, 2016. The extension of the application deadline date for this competition is intended to help affected eligible applicants compete fairly with other eligible applicants under this competition.

DATES:

Deadline for Transmittal of Applications: September 16, 2016.

Deadline for Intergovernmental Review: October 31, 2016.

SUPPLEMENTARY INFORMATION: On July 8, 2016, we published in the **Federal Register** (81 FR 44741) a notice inviting applications for new awards for FY 2016 for the Promise Neighborhoods competition. We are extending this competition to allow certain prospective eligible applicants more time to prepare and submit their applications.

Eligibility: The extension of the application deadline date in this notice applies to eligible applicants under the Promise Neighborhoods program that are (1) located in a Federally-declared disaster area, as determined by the Federal Emergency Management Agency (FEMA) (see *http://www.fema.gov/news/disasters.fema*); and (2) adversely affected by the severe storms and flooding in Louisiana that began on August 11, 2016.

In accordance with the application notice, an eligible organization for the Promise Neighborhoods program—

(1) Is representative of the geographic area proposed to be served;

(2) Is one of the following:

(a) A nonprofit organization that meets the definition of a nonprofit under 34 CFR 77.1(c), which may include a faith-based nonprofit organization.

(b) An institution of higher education as defined by section 101(a) of the Higher Education Act of 1965, as amended.

(c) An Indian tribe as defined in the application notice for this competition published by us in the **Federal Register** on July 8, 2016 (81 FR 44741);

(3) Currently provides at least one of the solutions from the applicant's proposed continuum of solutions in the geographic area proposed to be served; and

(4) Operates or proposes to work with and involve in carrying out its proposed project, in coordination with the school's LEA, at least one public elementary or secondary school located within the identified geographic area that the grant will serve.

In the case of an eligible applicant that is a partnership, the extension of the application deadline date applies if any entity required to be part of the partnership (*e.g.,* a nonprofit organization, an LEA, or a consortium of schools) are located in a Federally-declared disaster area, as determined by FEMA, and adversely affected by the severe storms and flooding in Louisiana that began on August 11, 2016.

An eligible applicant submitting an application under the extended deadline in this notice must provide in its application a certification that it meets the criteria for an extension and be prepared to provide appropriate supporting documentation, if requested. If such an eligible applicant is submitting its application electronically, the submission of the application serves as the eligible applicant's attestation that it meets the criteria for submitting an application under the extended deadline.

Note: Except for the deadline date, all information in the application notice for this competition remains the same.

Program Authority: Fund for the Improvement of Education, title V, part D, subpart 1, sections 5411 through 5413 of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (20 U.S.C. 7243–7243b).

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202. Telephone: (202) 453–5638. Email address: *PromiseNeighborhoods@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact persons listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: August 25, 2016.

Nadya Chinoy Dabby,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2016–21001 Filed 8–30–16; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Meeting Notice; Public Meeting of the Technical Guidelines Development Committee

AGENCY: U.S. Election Assistance Commission

ACTION: Public Meeting of the Technical Guidelines Development Committee

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. Appendix 2), notice is hereby given that the U.S. Election Assistance Commission's (EAC) Technical Guidelines Development Committee (TGDC) will meet in open session on Thursday, September 15, 2016 and Friday, September 16, 2016 at the National Institute of Standards and Technology (NIST) in Gaithersburg, Maryland.

DATES: The meeting will be held on Thursday, September 15, 2016, from 8:30 a.m. until 5:00 p.m., Eastern time (estimated based on speed of business), and Friday, September 16, 2016 from 8:30 a.m. to 12:00 p.m., Eastern time (estimated based on speed of business).

ADDRESS: The meeting will take place at the National Institute of Standards and Technology, 100 Bureau Drive, Building 101, West Square Room, Gaithersburg, Maryland 20899–8900. Members of the public wishing to attend the meeting must notify Gladys Arrisueno by c.o.b. Thursday, September 8, 2016, per instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Patricia Wilburg, NIST Voting Program, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8970, Gaithersburg, MD 20899–8930, telephone: (301) 975–6994 or *patricia.wilburg@nist.gov.*

SUPPLEMENTARY INFORMATION: The Technical Guidelines Development Committee will meet Thursday, September 15, 2016, from 8:30 a.m. until 5:00 p.m., Eastern time, and Friday, September 16, 2016 from 8:30 a.m. to 12:00 p.m., Eastern time. Discussions at the meeting will include the following topics: The Working Group and Constituency Groups activities since the February TGDC Meeting that include Cyber Security, Human Factors, Interoperability and Testing; the scope of the VVSG, Post-HAVA Voting System Requirements, Usability & Accessibility, and Security; and the VVSG 2.0 Project Charter. The full meeting agenda will be posted in advance at *http://vote.nist.gov/.* All sessions of this meeting will be open to the public.

The TGDC was established pursuant to 42 U.S.C 15361, to act in the public interest to assist the Executive Director of the Election Assistance Commission (EAC) in the development of voluntary voting system guidelines. Details regarding the TGDC's activities are available at *http://vote.nist.gov/.*

All visitors to the National Institute of Standards and Technology site will have to pre-register to be admitted. Anyone wishing to attend this meeting must register by c.o.b. Thursday, September 8, 2016, in order to attend. Please submit your name, time of arrival, email address and phone number to Gladys Arrisueno and she will provide you with instructions for admittance. Non-U.S. citizens must also submit their country of citizenship, title, employer/sponsor, and address. Gladys Arrisueno's email address is *gladys.arrisueno@nist.gov,* and her phone number is (301) 975–5220. If you are in need of a disability accommodation, such as the need for Sign Language Interpretation, please contact Patricia Wilburg by c.o.b Thursday, September 8, 2016. Patricia Wilburg's contact information is given in the **FOR FURTHER INFORMATION CONTACT** section above.

Members of the public may submit relevant written statements to the TGDC with respect to the meeting no later than 5:00 p.m. EDT on Thursday, September 8, 2016. Statements may be sent via email at *facaboards@eac.gov,* via standard mail addressed to the U.S. Election Assistance Commission, 1335 East West Highway, Suite 4300, Silver Spring, MD 20910, or by fax at 301–734–3108. All comments will also be posted on *http://vote.nist.gov/.*

This meeting will be open to the public.

Bryan Whitener,

Director of Communications & Clearinghouse, U.S. Election Assistance Commission.

[FR Doc. 2016–20901 Filed 8–30–16; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of partially-closed meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a partially-closed meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: September 30, 2016; 8:30 a.m. to 12:30 p.m.

ADDRESSES: The meeting will be held at the National Academy of Sciences, 2101 Constitution Avenue NW., Washington, DC, in the Lecture Room.

FOR FURTHER INFORMATION CONTACT: Information regarding the meeting agenda, time, location, and how to register for the meeting is available on the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.* A live video webcast and an archive of the webcast after the event are expected to be available at *http://whitehouse.gov/ostp/pcast.* The archived video will be available within one week of the meeting. Questions about the meeting should be directed to Ms. Jennifer Michael at *jmichael@ostp.eop.gov,* (202) 456–4444. Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from inside the White House, cabinet departments, and other Federal agencies. See the Executive Order at *http://www.whitehouse.gov/ostp/pcast.* PCAST is consulted about and provides analyses and recommendations concerning a wide range of issues where understandings from the domains of science, technology, and innovation may bear on the policy choices before the President. PCAST is co-chaired by Dr. John P. Holdren, Assistant to the President for Science and Technology, and Director, Office of Science and Technology Policy, Executive Office of the President, The White House; and Dr. Eric S. Lander, President, Broad Institute of the Massachusetts Institute of Technology and Harvard.

Type of Meeting: Open and Closed.

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology (PCAST) is scheduled to meet in open session on September 30, 2016, from 8:30 a.m. to 12:30 p.m.

Open Portion of Meeting: During this open meeting, PCAST is scheduled to discuss its studies on forensics, biodefense, and water science and technology. They will also hear from speakers who will remark on agriculture preparedness and soil sciences and others who will speak on data and justice. Additional information and the agenda, including any changes that arise, will be posted at the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.*

Closed Portion of the Meeting: PCAST may hold a closed meeting of approximately one hour with the President on September 30, 2016, which must take place in the White House for the President's scheduling convenience and to maintain Secret Service protection. Both meetings will be closed to the public because such portion of the meeting is likely to disclose matters that are to be kept secret in the interest of national defense or foreign policy under 5 U.S.C. 552b(c)(1).

Public Comments: It is the policy of the PCAST to accept written public comments of any length, and to accommodate oral public comments whenever possible. The PCAST expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

The public comment period for this meeting will take place on September 30, 2016, at a time specified in the meeting agenda posted on the PCAST Web site at *http://whitehouse.gov/ostp/pcast.* This public comment period is designed only for substantive commentary on PCAST's work, not for business marketing purposes.

Oral Comments: To be considered for the public speaker list at the meeting, interested parties should register to speak at *http://whitehouse.gov/ostp/pcast,* no later than 12:00 p.m. (Eastern Time) on September 23, 2016. Phone or email reservations will not be accepted. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of up to 15 minutes. If more speakers register than there is space available on the agenda, PCAST will randomly select speakers from among those who applied. Those not selected to present oral comments may always file written comments with the committee. Speakers are requested to bring at least 25 copies of their oral comments for distribution to the PCAST members.

Written Comments: Although written comments are accepted continuously, written comments should be submitted to PCAST no later than 12:00 p.m. (Eastern Time) on September 23, 2016, so that the comments may be made available to the PCAST members prior to this meeting for their consideration. Information regarding how to submit comments and documents to PCAST is available at *http://whitehouse.gov/ostp/pcast* in the section entitled "Connect with PCAST."

Please note that because PCAST operates under the provisions of FACA, all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST Web site.

Meeting Accommodations: Individuals requiring special accommodation to access this public meeting should contact Ms. Jennifer Michael at least ten business days prior to the meeting so that appropriate arrangements can be made.

Issued in Washington, DC, on August 25, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–20935 Filed 8–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Extension of a Currently Approved Information Collection for the Weatherization Assistance Program

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for OMB review and comment.

SUMMARY: The Department of Energy (DOE) has submitted to the Office of Management and Budget (OMB) for clearance, a proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995. The proposed collection will collect information on the status of grantee activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively and expeditiously.

DATES: Comments regarding this collection must be received on or before September 30, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4650.

ADDRESSES: Written comments should be sent to: Attention: Desk Officer for DOE; Office of Information and Regulatory Affairs (OIRA); Office of Management and Budget, New Executive Office Building, 725 17th St. NW., Room 10202; Washington, DC 20503–0009 or by; email at: *OIRA_submission@omb.eop.gov.*

And to: Christine Askew, EE–5W; U.S. Department of Energy; 1000 Independence Ave., SW.; Washington, DC 20585-1290, Phone: (202)586–8224; Fax: (202) 287–1992; Email: *Christine.Askew@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Christine Askew, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585–1290, Phone: (202)586–8224, Fax: (202) 287–1992; Email: *Christine.Askew@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5127 ; (2) Information Collection Request Title: "Weatherization Assistance Program (WAP)"; (3) Type of Request: Extension of a Currently Approved Information Collection; (4) Purpose: To collect information on the status of grantee activities, expenditures, and results, to ensure that program funds are being used appropriately, effectively and expeditiously (5) Annual Estimated Number of Respondents: 59; (6) Annual Estimated Number of Total Responses: 696; (7) Annual Estimated Number of Burden Hours: 2,088; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $0; (5) Annual Estimated Number of Respondents: 59; (6) Annual Estimated Number of Total Responses: 696; (7) Annual Estimated Number of Burden Hours: 2,088; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $0.

Statutory Authority: Title V, Subtitle E of the Energy Independence and Security Act (EISA), Pub. L. 110–140 as amended (42 U.S.C. 17151 *et seq.*).

Issued in Washington, DC, on August 17, 2016.

AnnaMaria Garcia,

Program Manager, Office of Weatherization and Intergovernmental Program, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2016–20945 Filed 8–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Request for Information on the Availability of New Geothermal Electricity in the Salton Sea Area To Serve Regional Federal Load

AGENCY: Federal Energy Management Program (FEMP), Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Notice of availability and request for information.

SUMMARY: The Federal Energy Management Program Office (FEMP), within the U.S. Department of Energy (DOE), released on its Web site a Request for Information (RFI) on the availability of new construction geothermal electricity in the Salton Sea area to serve regional federal load. The purpose of the RFI is to gather industry input on options available to the Federal Government for a potential aggregated power purchase of 100–250 MW of new construction geothermal electricity generated in the Salton Sea area, within the Riverside and Imperial Counties of California, for delivery over a ten-year or twenty-year contract period to serve regional Federal load. The RFI can be found at *www.energy.gov/node/2000486.*

DATES: Written comments and information are requested on or before September 29, 2016.

ADDRESSES: Interested parties are to submit comments electronically to: *tracy.niro@ee.doe.gov.* Include "August 2016 Geothermal RFI" in the subject of the message.

Instructions: All submissions received must include "August 2016 Geothermal RFI" in the subject of the message. The notice is available at *www.energy.gov/node/2000486.*

FOR FURTHER INFORMATION CONTACT: Tracy Niro, U.S. Department of Energy, Federal Energy Management Program (EE–2L), 1000 Independence Avenue SW., Washington, DC 20585; email: *Tracy.Niro@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: FEMP released an RFI to gather information on the potential for an aggregated power purchase of 100–250 MW of new construction geothermal electricity generated in the Salton Sea area, which is located within the Riverside and Imperial Counties of California, for delivery over a ten-year or twenty-year contract period to serve regional Federal load located in one or more of the Arizona counties of: Pima, Pinal, Maricopa, Yuma, La Paz and/or the California counties of: Imperial, San Diego, Riverside, San Bernardino, Orange and Los Angeles. The RFI requests responders to provide information on potential new construction geothermal projects in the Salton Sea area and to describe details about those options such as whether the power would include any associated renewable energy certificates, the optimal term for any agreement, and whether transmission, congestion, or infrastructure issues might impact projects, among other things. The RFI is available on the FEMP Web site at: *www.energy.gov/node/2000486.*

FEMP invites all interested parties to submit in writing by September 29, 2016, comments and information on matters addressed in the notice.

Issued in Washington, DC, on August 25, 2016.

Timothy D. Unruh,

Program Director, Federal Energy Management Program, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–20944 Filed 8–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5296–014]

Champlain Spinners Power Company Inc., Champlain Spinners Power, LLC; Notice of Transfer of Exemption

1. By letter filed July 29, 2016, Eagle Creek Renewable Energy, LLC submitted

notice to the Commission that, through its subsidiary Eagle Creek Development Holdings, LLC, it has acquired Champlain Spinners Power Company Inc., the exemptee for the Champlain Spinners Project No. 5296, originally issued March 1, 1982.[1] In the course of the transaction, Champlain Spinners Power Company, Inc. converted its corporate form from a corporation into a limited liability company and transferred the exemption to Champlain Spinners Power, LLC. The project is located on the Champlain Canal in Washington County, New York. The transfer of an exemption does not require Commission approval.

2. Champlain Spinners Power, LLC is now the exemptee of the Champlain Spinners Project No. 5296. All correspondence should be forwarded to: Mr. Bernard Cherry, Champlain Spinners Power, LLC, c/o Eagle Creek Renewable Energy, LLC, 65 Madison Avenue, Suite 500, Morristown, NJ 07960.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20979 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–493–000]

Columbia Gas Transmission, LLC; Notice of Application

Take notice that on August 12, 2016, Columbia Gas Transmission, LLC (Columbia), having its principal place of business at 5151 San Felipe, Suite 2500, Houston, TX 77056 filed in the above referenced docket an application pursuant to section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization to install and operate compressions, pipeline and appurtenant facilities located in Louisa and Goochland Counties, Virginia, referred to as the Central Virginia Connector Project (Project), all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Tyler Brown, Senior Counsel, 5151 San Felipe, Suite 2500, Houston, TX 77056; by calling (713) 386–3797; by faxing (304) 357–2509; or by emailing *tbrown@cpg.com.*

Specifically, the applicant proposes the following modifications: (i) Replace unit at Louisa CS, (ii) convert replaced units to standby, (iii) increase horsepower (HP) by 2,080 HP, (iv) install 0.12 mile of 8-inch-diameter pipeline, (v) install station pipe and valve to make section at Boswell's Tavern bi-directional, and (vi) install meter station near Goochland CS. The increase in HP will provide an additional capacity of 45 million cubic feet per day (MMcf/d). The total cost of the Project is $52,387,031.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: September 15, 2016.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20974 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] 19 FERC ¶ 62,508 (1982), Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less and Dismissing Application for Preliminary Permit.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No., CD16–19–000]

Amador Water Agency; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On August 15, 2016, the Amador Water Agency filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Ione Hydroelectric Station Project would have an installed capacity of 447.6 kilowatts (kW) and would be located on an existing 16-inch-diameter gravity fed raw water transmission pipe. The project would be located near the City of Ione in Amador County, California.

Applicant Contact: Gene Mancebo, Amador Water Agency, 12800 Ridge Road, Sutter Creek, CA 95685, Phone No. (209) 257–5245.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) A proposed 90-foot long, 12-inch-diameter intake pipe, (2) a proposed 447.6-kW turbine parallel to and replacing the existing pressure reducing valve, (3) a proposed 260-foot-long 12-inch diameter outlet pipe emptying into the supply reservoir, and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 1,400 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar man-made water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff has preliminarily determined that the proposal satisfies the requirements for a qualifying conduit hydropower facility under 16 U.S.C. 823a, and is exempted from the licensing requirements of the FPA.

Comments and Motions to Intervene: The deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

The deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the "COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY" or "MOTION TO INTERVENE," as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the "eLibrary" link. Enter the docket number (*e.g.,* CD16–19–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20981 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] 18 CFR 385.2001–2005 (2015).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10887–027]

Climax Manufacturing Company; Notice of Application Accepted for Filing, Soliciting Comments, Protests and Motions To Intervene

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Extension of License Term.

b. *Project No.:* P–10887–027.

c. *Date Filed:* August 4, 2016.

d. *Licensee:* Climax Manufacturing Company.

e. *Name and Location of Project:* Carthage Paper Makers Hydroelectric Project, located on the Black River in Jefferson and Lewis counties, New York.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

g. *Licensee Contact Information:* Mr. Fred Goutremout, 30 Champion Street, Carthage, New York 13619, Phone: (315) 493–5518.

h. *FERC Contact:* Mr. Ashish Desai, (202) 502–8370, *Ashish.Desai@ferc.gov.*

i. Deadline for filing comments, motions to intervene and protests, is 30 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, and recommendations, using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–10887–027.

j. *Description of Proceeding:* The licensee, Climax Manufacturing Company, requests the Commission extend the term of the license by five years, from October 31, 2021 to October 31, 2026. The licensee received a 20-year license for the project on October 22, 1991. The licensee states that in order to facilitate a basin-wide relicensing approach with several other projects, it needs the five-year extension for the license term. The licensee states that it has consulted with the U.S. Fish and Wildlife Service (FWS) and New York State Department of Environmental Conservation (DEC), and coordinated with other licensees to develop a framework for relicensing. The licensee states that the FWS and the New York DEC support the process.

k. This notice is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the Docket number (P–10887–027) excluding the last three digits in the docket number field to access the notice. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

m. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

n. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20980 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2101–127]

Sacramento Municipal Utility District; Notice of Application Accepted for Filing, Soliciting Comments, Protests and Motions To Intervene

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project No.:* 2101–127.

c. *Date Filed:* May 25, 2016.

d. *Applicant:* Sacramento Municipal Utility District.

e. *Name of Project:* Upper American River Hydroelectric Project.

f. *Location:* The project is located on Silver Creek and the Rubicon and South Fork American rivers in El Dorado and Sacramento counties, California. The project occupies federal lands administered by the Bureau of Land Management and by the U.S. Forest Service within the Eldorado National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. David Hanson, Project Manager, Hydro Licensing & Permitting, Sacramento Municipal Utility District, P.O. Box 15830, Mail Stop K203, Sacramento, CA 95852–0830, (888) 742–7683.

i. *FERC Contact:* Mr. Rebecca Martin (202) 502–6052 or *Rebecca.Martin@ferc.gov.*

j. Deadline for filing comments, motions to intervene and protests, is 30 days from the issuance date of this notice. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, and recommendations, using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2101–127.

k. *Description of Request:* The applicant proposes to delete the Iowa Hill Pump Storage Development from its license. The licensee states that it is unlikely that the licensee would need any significant portion of the Iowa Hill Development's 400–MW capacity and that the estimated cost of construction is significantly higher than expected at the time of licensing. This proposal would not result in any physical or operational changes to the project. In addition, the licensee is requesting that the license provisions solely related to the Iowa Hill Development be deleted from the license.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the in the Public Reference Room, Room 2A, 888 First Street, NE., Washington, DC 20426. The filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the Docket number excluding the last three digits in the docket number field to access the notice. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20978 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2453–000]

Brady Interconnection, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Brady Interconnection, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is September 14, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC

Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20976 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–494–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Application

Take notice that on August 16, 2016, Transcontinental Gas Pipe Line Company, LLC (Transco), Post Office Box 1396, Houston, Texas 77251, filed in Docket No. CP16–494–000, an application pursuant to section 7(c) of the Natural Gas Act and Part 157 of the Commission's regulations requesting authorization of its Gulf Connector Expansion Project (Project) consisting of three new compressor stations totaling 30,650 horsepower in Wharton, San Patricio and Victoria Counties, Texas; a new interconnect with Cheniere Corpus Christi Pipeline, LLC's pipeline facilities in San Patricio County, Texas; and piping and valve modifications in Hardin and Wharton Counties, Texas to allow for bi-directional flow and related appurtenant facilities. The Project would cost approximately $167.4 million and would enable 475,000 dekatherms per day of incremental firm natural gas transportation, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this Application should be directed to Ingrid Germany, Rates & Regulatory, P.O. Box 1396, Houston, Texas 77251–1396, or call (713) 215–4015, or via eMail: *PipelineExpansion@Williams.com,* the toll-free Project telephone number (866) 455–9103, or the Project Web site at *www.williams.com/GulfConnector.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with he Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and ill not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link.

Comment Date: September 15, 2016

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20975 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC16–10–000]

Commission Information Collection Activities (FERC Form 80, FERC–550, and FERC–549); Comment Request

AGENCY: Federal Energy Regulatory Commission.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting these information collections (FERC Form 80 [Licensed Hydropower Development Recreation Report], FERC–550 [Oil Pipeline Rates-Tariff Filings], and FERC–549 [NGPA[1]

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[1] NGPA = Natural Gas Policy Act

Title III Transactions and NGA[2] Blanket Certificate Transaction]) to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** (81 FR 33499, 5/26/2016) requesting public comments. The Commission received no comments regarding any of the included information collections and is making this notation in its submittal to OMB.

DATES: Comments on the collections of information are due by September 30, 2016.

ADDRESSES: Comments filed with OMB, identified by the OMB Control Nos. 1902–0106 (FERC Form 80), 1902–0089 (FERC–550), or 1902–0086 (FERC–549) should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov,* Attention: Federal Energy Regulatory Commission Desk Officer.

A copy of the comments should also be sent to the Commission, in Docket No. IC16–10–000, by either of the following methods:

- *eFiling at Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Type of Request: Three-year extension of the information collection requirements for all collections described below with no changes to the current reporting requirements. Please note that each collection is distinct from the next.

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FERC Form 80, Licensed Hydropower Development Recreation Report

OMB Control No.: 1902–0106.

Abstract: FERC uses the information on the FERC Form 80 (also known as "FERC–80") to implement the statutory provisions of sections 4(a), 10(a), 301(a), 304 and 309 of the Federal Power Act (FPA), 16 U.S.C. 797, 803, 825c and 825h. FERC's authority to collect this information comes from section 10(a) of the FPA which requires the Commission to be responsible for ensuring that hydro projects subject to FERC jurisdiction are consistent with the comprehensive development of the nation's waterway for recreation and other beneficial public uses. In the interest of fulfilling these objectives, FERC expects licensees subject to its jurisdiction to recognize the resources that are affected by their activities and to play a role in protecting such resources.

FERC Form 80 is a report on the use and development of recreational facilities at hydropower projects licensed by the Commission. Applications for amendments to licenses and/or changes in land rights frequently involve changes in resources available for recreation. FERC utilizes the FERC Form 80 data when analyzing the adequacy of existing public recreational facilities and when processing and reviewing proposed amendments to help determine the impact of such changes. In addition, FERC staff uses the FERC Form 80 data when conducting inspections of licensed projects and in evaluating compliance with various license conditions and in identifying recreational facilities at hydropower projects.

The data which FERC Form 80 requires are specified by Title 18 of the Code of Federal Regulations (CFR) under 18 CFR 8.11 and 141.14 (and are discussed at *http://www.ferc.gov/docs-filing/forms.asp#80*).

FERC collects the FERC Form 80 once every six years. The last collection was due on April 1, 2015, for data compiled during the 2014 calendar year. The next collection of the FERC Form 80 is due on April 1, 2021, with subsequent collections due every sixth year, for data compiled during the previous calendar year.

The Commission updated the format for the general instructions section of the form for improved readability. Specifically, FERC split a long paragraph into several smaller paragraphs.

FERC made no changes to the instructions, form, or glossary.

Type of Respondent: Hydropower project licensees.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden for the information collection as:

FERC FORM 80—LICENSED HYDROPOWER DEVELOPMENT RECREATION REPORT

Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response[3] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
400	0.167	[4] 67	[5] 3 hrs.; $224	201 hrs.; $14,974.50	$37.44

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[2] NGA = Natural Gas Act

[3] The estimates for cost per response are derived using the 2016 FERC average salary plus benefits of $154,647/year (or $74.50/hour). Commission staff finds that the work done for this information collection is typically done by wage categories similar to those at FERC.

[4] This figure is rounded from 66.8.

[5] This figure is rounded from $223.50.

FERC–550—Oil Pipelines Rates—Tariff Filings

OMB Control No.: 1902–0089.

Abstract: FERC–550 is required to implement the sections of the Interstate Commerce Act (ICA) (49 U.S.C. 1, *et seq.*, 49 App. U.S.C. 1–85). The Commission's regulatory jurisdiction over oil pipelines includes:

- Regulation of rates and practices of oil pipeline companies engaged in interstate transportation;
- establishment of equal service conditions to provide shippers with equal access to pipeline transportation;
- establishment of reasonable rates for transporting petroleum and petroleum products by pipeline.

The filing requirements for oil pipeline tariffs and rates[6] put in place by the FERC–550 data collection provide the Commission with the information it needs to analyze proposed tariffs, rates, fares, and charges of oil pipelines and other carriers in connection with the transportation of crude oil and petroleum products. The Commission uses this information to determine whether the proposed tariffs and rates are just and reasonable.

Type of Respondent: Oil Pipelines.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden[7] and cost for the FERC–550 information collection as follows:

FERC–550—OIL PIPELINES RATES—TARIFF FILINGS

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response[8] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
FERC–550	208	3.68	765	7.815 hrs.; $582.22	5,978 hrs.; $445,396	$2,141.33

FERC–549—NGPA Title III Transactions and NGA Blanket Certificate Transaction

OMB Control No.: 1902–0086.

Abstract: FERC–549 is required to implement the statutory provisions governed by Sections 311 and 312 of the Natural Gas Policy Act (NGPA) (15 U.S.C. 3371–3372) and Section 7 of the Natural Gas Act (NGA) (15 U.S.C. 717f). The reporting requirements for implementing these provisions are contained in 18 CFR part 284.

Transportation by Interstate Pipelines

In 18 CFR 284.102(e) the Commission requires interstate pipelines to obtain proper certification in order to ship natural gas on behalf of intrastate pipelines and local distribution companies (LDC). This certification consists of a letter from the intrastate pipeline or LDC authorizing the interstate pipeline to ship gas on its behalf. In addition, interstate pipelines must obtain from its shippers certifications including sufficient information to verify that their services qualify under this section.

Rates and Charges for Intrastate Pipelines

18 CFR 284.123(b) provides that intrastate gas pipeline companies file for Commission approval of rates for services performed in the interstate transportation of gas. An intrastate gas pipeline company may elect to use rates contained in one of its then effective transportation rate schedules on file with an appropriate state regulatory agency for intrastate service comparable to the interstate service or file proposed rates and supporting information showing the rates are cost based and are fair and equitable. It is the Commission policy that each pipeline must file at least every five years to ensure its rates are fair and equitable. Depending on the business process used, either 60 or 150 days after the application is filed, the rate is deemed to be fair and equitable unless the Commission either extends the time for action, institutes a proceeding or issues an order providing for rates it deems to be fair and equitable.

18 CFR 284.123(e) requires that within 30 days of commencement of new service any intrastate pipeline engaging in the transportation of gas in interstate commerce must file a statement that includes the interstate rates and a description of how the pipeline will engage in the transportation services, including operating conditions. If an intrastate gas pipeline company changes its operations or rates, it must amend the statement on file with the Commission. Such amendment is to be filed not later than 30 days after commencement of the change in operations or change in rate election.

Code of Conduct

The Commission's regulations at 18 CFR 284.288 and 284.403 provide that applicable sellers of natural gas adhere to a code of conduct when making gas sales in order to protect the integrity of the market. As part of this code, the Commission imposes a record retention requirement on applicable sellers to "retain, for a period of five years, all data and information upon which it billed the prices it charged for natural gas it sold pursuant to its market based sales certificate or the prices it reported for use in price indices." FERC uses these records to monitor the jurisdictional transportation activities and unbundled sales activities of interstate natural gas pipelines and blanket marketing certificate holders.

The record retention period of five years is necessary due to the importance of records related to any investigation of possible wrongdoing and related to assuring compliance with the codes of conduct and the integrity of the market. The requirement is necessary to ensure consistency with the rule prohibiting market manipulation (regulations adopted in Order No. 670, implementing the EPAct 2005 anti-manipulation provisions) and the generally applicable five-year statute of limitations where the Commission seeks civil penalties for violations of the anti-manipulation rules or other rules, regulations, or orders to which the price data may be relevant. Failure to have this information available would mean the Commission is unable to perform its regulatory functions and to monitor and evaluate transactions and operations of interstate pipelines and blanket marketing certificate holders.

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[6] 18 CFR parts 341–348.

[7] The one-time burden imposed by Order 780 (issued May 16, 2013, in Docket No. RM12–15–000; 78 FR 32090, 5/29/2013) has been completed and is not included.

[8] The estimates for cost per response are derived using the FERC 2016 average salary plus benefits of $154,647/year (or $74.50/hour). Commission staff finds that the work done for this information collection is typically done by wage categories similar to those at FERC.

Market-Based Rates for Storage

In 2006 the Commission amended its regulations to establish criteria for obtaining market-based rates for storage services offered under 18 CFR 284.501–505. First, the Commission modified its market-power analysis to better reflect the competitive alternatives to storage. Second, pursuant to the Energy Policy Act of 2005, the Commission promulgated rules to implement section 4(f) of the Natural Gas Act, to permit underground natural gas storage service providers that are unable to show that they lack market power to negotiate market-based rates in circumstances where market-based rates are in the public interest and necessary to encourage the construction of the storage capacity in the area needing storage services, and where customers are adequately protected. These revisions are intended to facilitate the development of new natural gas storage capacity while protecting customers.

Type of Respondent: Gas pipelines.

Estimate of Annual Burden: The Commission estimates the annual public reporting burden for the information collection as:

FERC–549—NGPA TITLE III TRANSACTIONS AND NGA BLANKET CERTIFICATE TRANSACTION

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Transportation by Interstate Pipelines[9].	75	2	150	3 hrs.[10]; $386.82	450 hrs.; $58,023	$773.64
Rates and Charges for Intrastate Pipelines[11].	50	1	50	50 hrs.; $5,084.50[12]	2,500 hrs.; $254,225	5,084.50
Code of Conduct[13 14]	222	1	222	1 hr.; $128.94[10]	222 hrs.; $28,624.68	128.94
Market-Based Rates[15]	4	1	4	350 hrs.; $45,129[10]	1,400 hrs.; $180,516	45,129
Total			426		4,572 hrs.; $521,388.68.	

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20977 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12796–004]

City of Wadsworth, Ohio; Notice of Teleconference

a. *Project Name and Number:* R.C. Byrd Hydroelectric Project No. 12796.

b. *Date and Time of Meeting:* Tuesday, September 20, 2016 at 2:00 p.m. (Eastern Daylight Time).

c. *FERC Contact:* Andy Bernick, *andrew.bernick@ferc.gov* or (202) 502–8660.

d. *Purpose of Meeting:* Commission staff will hold a teleconference to discuss: (1) Additional information needs regarding listed freshwater mussel species filed by U.S. Fish and Wildlife Service's Pennsylvania Field Office (FWS) on June 16, 2016; and (2) the response to FWS' request, filed by American Municipal Power, Inc. (agent for the City of Wadsworth, Ohio) on July 15, 2016.

e. All local, state, and federal agencies, Indian tribes, and other interested entities are invited to participate by phone. Please call Andy Bernick at (202) 502–8660 by Tuesday, September 13, 2016, to RSVP and to receive specific instructions on how to participate.

Dated: August 24, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20971 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–141–000.

Applicants: Luning Energy Holdings LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Luning Energy Holdings LLC.

Filed Date: 8/25/16.

Accession Number: 20160825–5050.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: EG16–142–000.

Applicants: Luning Energy LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Luning Energy LLC.

Filed Date: 8/25/16.

Accession Number: 20160825–5051.

Comments Due: 5 p.m. ET 9/15/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1818–012; ER10–1817–013; ER10–1819–014; ER10–1820–017.

Applicants: Public Service Company of Colorado, Southwestern Public Service Company, Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.

Description: Supplement to January 14, 2016 Triennial Market Power

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[9] 18 CFR 284.102(e).

[10] The average hourly cost (salary plus benefits) is $128.94. The BLS wage category code is 23–0000 (lawyers). This figure is also taken from the Bureau of Labor Statistics, May 2015 figures at *http://www.bls.gov/oes/current/naics2_22.htm*.a

[11] 18 CFR 284.123(b),(e).

[12] The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * $101.69 per Hour = Average Cost per Response. The hourly average of $101.69 assumes equal time is spent by an economist and lawyer. The average hourly cost (salary plus benefits) is: $74.43 for economists (occupation code 19–3011) and $128.94 for lawyers (occupation code 23–0000). (The figures are taken from the Bureau of Labor Statistics, May 2015 figures at *http://www.bls.gov/oes/current/naics2_22.htm*).

[13] A portion of these responses includes recordkeeping burden.

[14] 18 CFR 284.288, 403.

[15] 18 CFR 284.501–505.

Analysis and Notice of Change in Status of Public Service Company of Colorado, et al.

Filed Date: 8/24/16.

Accession Number: 20160824–5268.

Comments Due: 5 p.m. ET 10/24/16.

Docket Numbers: ER15–2589–002.

Applicants: CPV Shore, LLC.

Description: Compliance filing: Compliance Filing of Reactive Power Service Rate Schedule to be effective 1/1/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5133.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–521–002.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2016–08–25 Att Y align with PRA Compliance to be effective 2/12/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5136.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2169–001.

Applicants: Algonquin SKIC 20 Solar, LLC.

Description: Tariff Amendment: Amendment to Application for Initial Tariff to be effective 7/14/2016.

Filed Date: 8/24/16.

Accession Number: 20160824–5225.

Comments Due: 5 p.m. ET 9/14/16.

Docket Numbers: ER16–2226–001.

Applicants: McHenry Battery Storage, LLC.

Description: Tariff Amendment: Supplement to McHenry Battery Storage Petition for Market-Based Rate Authority to be effective 7/19/2016.

Filed Date: 8/24/16.

Accession Number: 20160824–5226.

Comments Due: 5 p.m. ET 9/14/16.

Docket Numbers: ER16–2227–001.

Applicants: Kelly Creek Wind, LLC.

Description: Tariff Amendment: Kelly Creek Wind Supplement to Petition for Market-Based Rate Authority to be effective 9/17/2016.

Filed Date: 8/24/16.

Accession Number: 20160824–5228.

Comments Due: 5 p.m. ET 9/14/16.

Docket Numbers: ER16–2289–001.

Applicants: Golden Fields Solar I, LLC.

Description: Tariff Amendment: Supplement to App. for MBR Authorization in Response to Informal Staff Request to be effective 8/1/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5173.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2477–000.

Applicants: AES Alamitos, LLC.

Description: § 205(d) Rate Filing: AES Alamitos Tariff Update Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5137.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2478–000.

Applicants: AES Energy Storage, LLC.

Description: § 205(d) Rate Filing: AES Energy Strg Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5138.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2479–000.

Applicants: AES ES Tait, LLC.

Description: § 205(d) Rate Filing: AES ES Tait Tariff Update Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5139.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2480–000.

Applicants: AES Huntington Beach, L.L.C.

Description: § 205(d) Rate Filing: AES Huntington Bch Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5144.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2481–000.

Applicants: AES Laurel Mountain, LLC.

Description: § 205(d) Rate Filing: AES Laurel Mtn Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5147.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2482–000.

Applicants: AES Redondo Beach, L.L.C.

Description: § 205(d) Rate Filing: AES Redondo Bch Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5148.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2483–000.

Applicants: Mountain View Power Partners, LLC.

Description: § 205(d) Rate Filing: Mountain View Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5149.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2484–000.

Applicants: Mountain View Power Partners IV, LLC.

Description: § 205(d) Rate Filing: Mtn View IV Tariff Updates Filing to be effective 8/26/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5150.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2485–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2016–08–25 DSHBAOA with APS to be effective 10/25/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5152.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2486–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2502R1 Osage Wind/OG&E Facilities Construction Agreement to be effective 8/8/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5153.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2487–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: Resubmitted SA 358—Construction Agree w/PAC for Siphon-Pingree Line Rebuild to be effective 8/8/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5157.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2488–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1771R6 NPPD NITSA NOA Notice of Cancellation to be effective 6/1/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5162.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2489–000.

Applicants: Brady Interconnection, LLC.

Description: Baseline eTariff Filing: Brady, Brady II, and Brady Interconnection, LLC Shared Facilities Agreement to be effective 10/1/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5164.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: ER16–2490–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: SVEC ? Ancillary Services Agreement to be effective 9/1/2016.

Filed Date: 8/25/16.

Accession Number: 20160825–5168.

Comments Due: 5 p.m. ET 9/15/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20972 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–492–000]

EcoEléctrica, L.P.; Notice of Application

Take notice that on July 11, 2016, EcoEléctrica, L.P. (EcoEléctrica), Road 337, Km. 3.7, Bo. Tallaboa Poniente, Peñuelas, PR 00624, filed an application in Docket No. CP16–492–000 under section 3 of the Natural Gas Act (NGA), and Part 153 and 380 of the Commission's regulations for an amendment to the authorization granted by the Commission on May 15, 1996 in Docket No. CP95–35–000, as subsequently amended on April 16, 2009 in Docket No. CP95–35–001, and on June 19, 2014 in Docket No. CP13–516–000. EcoEléctrica requests authorization to amend its current NGA Section 3 authorization to use inherent spare capacity within the existing LNG vaporizers, to supply the Puerto Rico Electric Power Authority (PREPA) an additional 93 million standard cubic feet (MMscf/d) of natural gas, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any questions regarding this application should be directed to Jaime L. Sanabria, EcoEléctrica, L.P., Road 337, Km. 3.7, Bo. Tallaboa Poniente, Peñuelas, PR 00624, (787) 759–0202, or by email at *jaime.sanabria@ecoelectrica.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: September 15, 2016.

Dated: August 25, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–20973 Filed 8–30–16; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1159]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before September 30, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called "Currently Under Review," (3) click on the downward-pointing arrow in the "Select Agency" box below the "Currently Under Review" heading, (4) select "Federal Communications Commission" from the list of agencies presented in the "Select Agency" box, (5) click the "Submit" button to the right of the "Select Agency" box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1159.

Title: Part 27—Miscellaneous Wireless Communications Services in the 2.3 GHz Band.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 158 respondents and 2,406 responses.

Estimated Time per Response: 0.5–40 hours.

Frequency of Response: Recordkeeping requirement, Third Party Disclosure, and on occasion and quarterly reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is 47 U.S.C. 154, 301, 302(a), 303, 309, 332, 336, and 337 unless otherwise noted.

Total Annual Burden: 24,714 hours.

Annual Cost Burden: $546,450.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The information filed by Wireless Communications Service (WCS) licensees in support of their construction notifications will be used to determine whether licensees have complied with the Commission's performance benchmarks. Further, the information collected by licensees in support of their coordination obligations will help avoid harmful interference to Satellite Digital Audio Radio Service (SDARS), Aeronautical Mobile Telemetry (AMT) and Deep Space Network (DSN) operations in other spectrum bands.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2016–20870 Filed 8–30–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comments on its proposal to extend, for three years, the current PRA clearance for its portion of the information collection requirements contained in the Consumer Financial Protection Bureau's Regulation N (the Mortgage Acts and Practices—Advertising Rule). The FTC shares enforcement of Regulation N with the Consumer Financial Protection Bureau ("CFPB"). This clearance expires on December 31, 2016.

DATES: Comments must be received on or before October 31, 2016.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the Supplementary Information section below. Write "Regulation N: FTC File No. P134811; K05" on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/regulationnpra* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the collection of information and supporting documentation should be addressed to Carole L. Reynolds, Attorney, Division of Financial Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., CC–10232, Washington, DC 20580, (202) 326–3230.

SUPPLEMENTARY INFORMATION:

Proposed Information Collection Activities

Under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3520, federal agencies must get OMB approval for each collection of information they conduct, sponsor, or require. "Collection of information" means agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the FTC's existing PRA clearance for the information collection requirements associated with the CFPB's Regulation N (Mortgage Acts and Practices—Advertising), 12 CFR 1014.[1] The FTC and the CFPB share enforcement authority for Regulation N and thus the CFPB has incorporated into its recently approved burden estimates for Regulation N one half of its burden estimates.[2]

The FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. All comments must be received on or before October 31, 2016.

The FTC's Mortgage Acts and Practices—Advertising Rule, 16 CFR 321, was issued by the FTC on July 19, 2011, at *www.ftc.gov,* published in the **Federal Register**, 76 FR 43845, and became effective on August 19, 2011. The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act)[3] substantially changed the federal legal framework for financial services providers. Among the changes, the Dodd-Frank Act transferred to the CFPB the Commission's rulemaking authority under section 626 of the 2009 Omnibus Appropriations Act on July 21, 2011. As a result, the CFPB republished the Mortgage Acts and Practices—Advertising Rule, at 12 CFR 1014, which became effective December 30, 2011. 76 FR 78130. Thereafter, the Commission rescinded its Rule, on and effective April 13, 2012. 77 FR 22200. Under the Dodd-Frank Act, the FTC retains its authority to bring law enforcement actions to enforce Regulation N.[4] Regulation N's recordkeeping requirements constitute a "collection of information"[5] for purposes of the PRA.[6] The Rule does not impose a disclosure requirement.

Regulation N requires covered persons to retain: (1) Copies of materially different commercial communications and related materials, regarding any term of any mortgage credit product, that the person made or disseminated during the relevant time period; (2) documents describing or evidencing all mortgage credit products available to consumers during the relevant time period; and (3) documents describing or evidencing all additional products or services (such as credit insurance or credit disability insurance) that are or may be offered or provided with the mortgage credit products available to consumers during the relevant time period. A failure to keep such records would be an independent violation of the Rule.

Commission staff believes these recordkeeping requirements pertain to records that are usual and customary and kept in the ordinary course of business for many covered persons, such as mortgage brokers, lenders, and servicers; real estate brokers and agents; home builders, and advertising agencies.[7] As to these persons, the retention of these documents does not constitute a "collection of information," as defined by OMB's regulations that implement the PRA.[8] Certain other covered persons such as lead generators and rate aggregators may not currently maintain these records in the ordinary course of business.[9] Thus, the recordkeeping requirements for those persons would constitute a "collection of information."

The information retained under the Rule's recordkeeping requirements is used by the Commission to substantiate compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

Burden Statement

Estimated total annual hours burden: 1,500 hours (for the FTC).

Commission staff estimates that the Rule's recordkeeping requirements will affect approximately 1,000 persons[10] who would not otherwise retain such records in the ordinary course of business. As noted, this estimate includes lead generators and rate aggregators that may provide commercial communications regarding mortgage credit product terms.[11] Although the Commission cannot estimate with precision the time required to gather and file the required records, it is reasonable to assume that covered persons will each spend approximately 3 hours per year to do these tasks, for a total of 3,000 hours (1,000 persons × 3 hours). Since the FTC shares enforcement authority with the CFPB for Regulation N, the FTC's allotted PRA burden is 1,500 annual hours.[12]

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[1] The OMB Control Number for the FTC's existing PRA clearance associated with Regulation N is 3084–0156.

[2] The CFPB clearance for their information collections associated with Regulation N was approved by the OMB on September 30, 2015 (OMB Control Number 3170–0009) through September 30, 2018.

[3] Public Law 111–203, 124 Stat. 1376 (2010).

[4] The Commission also retained its authority to enforce the Mortgage Acts and Practices—Advertising Rule from the Rule's issuance in July 2011 until the CFPB's republished rule, Regulation N, became effective on December 30, 2011.

[5] Section 1014.5 of the Rule sets forth the recordkeeping requirements.

[6] *See* 44 U.S.C. 3502(3)(A).

[7] Some covered persons, particularly mortgage brokers and lenders, are subject to state recordkeeping requirements for mortgage advertisements. *See, e.g.,* Fla. Stat. 494.00165 (2016); Ind. Code Ann. 23–2–5–18 (2016); Kan. Stat. Ann. 9–2208 (2015); Minn. Stat. 58.14 (2015); Wash. Rev. Code 19.146.060 (2015). Many mortgage brokers, lenders (including finance companies), and servicers are subject to state recordkeeping requirements for mortgage transactions and related documents, and these may include descriptions of mortgage credit products. *See, e.g.,* Mich. Comp. Laws Serv. 445.1671 (2016); N.Y. Banking Law 597 (Consol. 2015); Tenn. Code Ann. 45–13–206 (2015). Lenders and mortgagees approved by the Federal Housing Administration must retain copies of all print and electronic advertisements and promotional materials for a period of two years from the date the materials are circulated or used to advertise. *See* 24 CFR 202. Various other entities, such as real estate brokers and agents, home builders, and advertising agencies can be indirectly covered by state recordkeeping requirements for mortgage advertisements and/or retain ads to demonstrate compliance with state law. *See, e.g.,* 76 Del. Laws, c. 421, § 1.

[8] *See* 44 U.S.C. 3502(3)(A); 5 CFR 1320.3(b)(2).

[9] *See, e.g., United States* v. *Intermundo Media, LLC, dba Delta Prime Refinance,* No. 1:14–cv–2529 (D. Colo. filed Sept. 12, 2014) (D. Colo. Oct.7, 2014) (stipulated order for permanent injunction and civil penalty judgment), *available at https://www.ftc.gov/system/files/documents/cases/140912delta primestiporder.pdf.* The complaint charged this lead generator with numerous violations of Regulation N, including recordkeeping, and of other federal mortgage advertising mandates.

[10] No general source provides precise numbers of the various categories of covered persons. Commission staff, therefore, has used the following sources and inputs to arrive at this estimated total: 1,000 lead generators and rate aggregators, based on staff's administrative experience.

[11] The Commission does not know what percentage of these persons are, in fact, engaged in covered conduct under the Rule, *i.e.,* providing commercial communications about mortgage credit product terms. For purposes of these estimates, the Commission has assumed all of them are covered by the recordkeeping provisions and are not retaining these records in the ordinary course of business.

[12] This estimate reflects a decrease in burden compared to prior FTC estimates, because many

Estimated labor costs: $21,570.

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff further assumes that office support file clerks will handle the Rule's record retention requirements at an hourly rate of $14.38.[13] Based upon the above estimates and assumptions, the total annual labor cost to retain and file documents, for the FTC's allotted burden, is $21,570 (1,500 hours × $14.38 per hour).

Absent information to the contrary, staff anticipates that existing storage media and equipment that covered persons use in the ordinary course of business will satisfactorily accommodate incremental recordkeeping under the Rule. Accordingly, staff does not anticipate that the Rule will require any new capital or other non-labor expenditures.

Request for Comments

You can file a comment online or on paper. Write "Regulation N: FTC File No. P134811; K05" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/regulationnpra* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov,* you also may file a comment through that Web site.

If you file your comment on paper, write "Regulation N: FTC File No. P134811; K05" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610, (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610, (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 31, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Acting General Counsel.

[FR Doc. 2016–20933 Filed 8–30–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From QAISys, Inc.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from QAISys, Inc. of its status as a PSO, and has delisted the PSO accordingly. QAISys, Inc. submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on August 10, 2016.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ,

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entities can be indirectly covered by state recordkeeping requirements for mortgage advertisements and/or retain ads to demonstrate compliance with state law, as discussed above. *See supra* note 6. The FTC notes that the CFPB's recent information collection filing with OMB for Regulation N also reflects the view that, in large part, most entities either retain records in the ordinary course of business or to demonstrate compliance with other laws. *See generally* Bureau of Consumer Financial Protection, Agency Information Collection Activities: Submission for OMB Review; Comment Review, 80 FR 45645 (July 31, 2015), *available at https://www.gpo.gov/fdsys/pkg/FR-2015-07-31/pdf/2015-18809.pdf.*

[13] This estimate is based on mean hourly wages for office support file clerks provided by the Bureau of Labor Statistics. *See* U.S. Bureau of Labor Statistics, Occupational Employment and Wages—May 2015, table 1 ("National employment and wage data from the Occupational Employment Statistics survey by occupation"), released Mar. 30, 2016, *available at http://www.bls.gov/news.release/pdf/ocwage.pdf.*

5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the QAISys, Inc., PSO number P0161, to voluntarily relinquish its status as a PSO. Accordingly, QAISys, Inc. was delisted effective at 12:00 Midnight ET (2400) on August 10, 2016. AHRQ notes that that QAISys, Inc. submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on July 28, 2016. In addition, QAISys, Inc., P0046, was previously listed as a PSO in 2009; AHRQ accepted its request for voluntary relinquishment in 2013.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov.*

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–20912 Filed 8–30–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2495]

Submission of Warning Plans for Cigars; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Submission of Warning Plans for Cigars." The draft guidance, when finalized, will help those involved in the manufacture, distribution, and sale of cigars in the United States understand the new cigar warning plan requirements under FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance reiterates the required health warning statements and the requirements for random display and distribution that should be provided in cigar warning plans, and, when finalized, will help persons determine who should submit a warning plan, when a plan must be submitted, and what information should be included when submitting a plan.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–2495 for "Submission of Warning Plans for Cigars." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Submission of Warning Plans for Cigars."

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product as subject to FDA regulatory authority ("deeming") (section 901(b) of the FD&C Act (21 U.S.C. 387a)). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to cigars, among other products (81 FR 28973). Among the requirements that now apply to cigars are health warning statements prescribed under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), which permits restrictions on the sale and distribution of tobacco products that are "appropriate for the protection of public health." The regulation specifies the health warning statements to be displayed and also requires the submission of warning plans that provide for the random, equal display and random distribution of the statements on cigar packaging and advertising.

The draft guidance discusses the regulatory requirements to submit warning plans, who submits a warning plan, the scope of a warning plan, when to submit a warning plan, what information should be submitted in a warning plan, where to submit a warning plan, and what approval of a warning plan means.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on cigar warning plans. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 1143 have been approved under OMB control number 0910–0768.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20913 Filed 8–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0545]

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance document is notifying blood establishments that collect Whole Blood and blood components, that FDA has determined Zika virus (ZIKV) to be a relevant transfusion-transmitted infection (RTTI) and provides FDA's assessment. The guidance also provides recommendations to reduce the risk of transmission of ZIKV by Whole Blood and blood components. The guidance applies to the collection of Whole Blood and blood components. The guidance does not apply to the collection of Source Plasma. The guidance supersedes the February 2016 document entitled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry" (February 2016 guidance), and the March 2016 document entitled, "Questions and Answers Regarding 'Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry' " no later than 12 weeks after the date of the issuance of this guidance. Implementation of the guidance will be immediate for blood establishments that collect Whole Blood and blood components in States and territories with local transmission of ZIKV by mosquitos, and will be phased in over 4 to 12 weeks in other States and territories using a tiered, risk-based approach. Blood establishments should follow the recommendations in the February 2016 guidance until the recommendations in the guidance document have been fully implemented.

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately because the

Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–0545 for "Revised Recommendations for Reducing the Risk of Zika Virus; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry." The guidance is notifying blood establishments that collect Whole Blood and blood components that FDA has determined ZIKV to be an RTTI under 21 CFR 630.3(h)(2) and provides FDA's assessment. The guidance provides recommendations to reduce the risk of transmission of ZIKV by Whole Blood and blood components. The guidance does not apply to the collection of Source Plasma, which is used for further manufacture of plasma-derived products. If, based upon the available scientific evidence, the risk of ZIKV transmission by blood and blood components significantly changes, FDA may update the recommendations as warranted. In making this determination, FDA will consider available epidemiologic and other scientific evidence.

The guidance supersedes the February 2016 guidance entitled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus; Guidance for Industry" and the March 2016 guidance entitled, "Questions and Answers Regarding 'Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry' " no later than 12 weeks after the date of the issuance of this guidance. Implementation of the guidance will be immediate for blood establishments that collect Whole Blood and blood components in States and territories with local transmission of ZIKV by mosquitos, and will be phased in over 4 to 12 weeks in other States and territories using a tiered, risk-based approach. Blood establishments should follow the recommendations in the February 2016 guidance until they fully implement the recommendations in the guidance document currently being issued.

ZIKV is an arbovirus from the Flaviviridae family, genus *Flavivirus.* It is transmitted to humans primarily by the *Aedes aegypti* mosquito, but it may also be transmitted by the *Aedes albopictus* mosquito.

The global ZIKV epidemic expanded in the region of the Americas by early

2015 when the first local transmission was reported in Brazil. Local transmission of ZIKV has also been reported in areas outside of the Americas, including the Pacific Islands of Samoa, American Samoa, Marshall Islands and Tonga, and Cape Verde in Africa, and there are now at least 50 countries and territories worldwide with active local transmission of the virus.

The first local transmission of ZIKV in the United States was reported from Puerto Rico in December 2015, and soon thereafter local transmission was also reported in American Samoa and the U.S. Virgin Islands. In July 2016, the first cases of local transmission of ZIKV occurring in the continental United States were reported from Miami-Dade County in Florida. The possibility of further geographic spread of ZIKV exists in regions where the *Aedes aegypti*, and possibly the *Aedes albopictus*, mosquito is present. In January 2016, ZIKV disease was added to the list of nationally notifiable conditions in the United States as a subtype of Arboviral diseases.

The most common ZIKV disease symptoms include fever, arthralgia, maculopapular rash, and conjunctivitis. In addition, neurological manifestations and congenital anomalies have been associated with ZIKV disease outbreaks. ZIKV infection has been associated with Guillain-Barré syndrome. ZIKV infection during pregnancy is a cause of microcephaly and other serious fetal brain anomalies. Other problems have been detected in pregnancies and among fetuses and infants infected with ZIKV before birth, such as miscarriage, stillbirth, absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth; however, the full clinical spectrum of the effects of ZIKV infection during pregnancy is not yet known.

FDA has identified ZIKV as a transfusion-transmitted infection under § 630.3(*l*) and RTTI under § 630.3(h)(2). This determination is based on the severity of the disease, risk of transfusion-transmission by blood and blood components, the availability of appropriate screening measures, and significant incidence and prevalence affecting the potential donor population.

The guidance recommends that blood establishments test all donations collected in the United States and its territories with an investigational individual donor nucleic acid test (ID–NAT) for ZIKV under an investigational new drug application (IND), or when available, a licensed test. Alternatively, blood establishments may implement pathogen reduction technology for platelets and plasma using an FDA-approved pathogen reduction device as specified in the Instructions for Use of the device. If an FDA-approved pathogen reduction device becomes available for Whole Blood or red blood cells, blood establishments may implement pathogen reduction technology for such products rather than testing the donations. Blood establishments implementing these measures may discontinue providing donor educational material with respect to ZIKV and screening donors for ZIKV risk factors such as travel history and deferring them as previously recommended in the February 2016 guidance. Under 21 CFR 630.10(a), if a donor volunteers a recent history of ZIKV infection, a blood establishment must not collect blood or blood components from that donor. For such donors, the guidance recommends a deferral period of 120 days after a positive viral test or the resolution of symptoms, whichever timeframe is longer.

FDA recommends that blood establishments implement the recommendations in the guidance as follows: (1) Blood establishments that collect Whole Blood and blood components in U.S. States and territories with one or more reported locally acquired mosquito-borne cases of ZIKV should implement the recommendations immediately. Blood establishments should cease blood collection until testing or the use of pathogen reduction technology is implemented, consistent with the recommendations in the guidance. As of the date of issuance of the guidance, the recommendations applies to blood establishments that collect Whole Blood and blood components in Florida and Puerto Rico; (2) because of their proximity to areas with locally acquired mosquito-borne cases of ZIKV or because of other epidemiological linkage to ZIKV, such as the number of travel-associated cases reported in a State, blood establishments that collect Whole Blood and blood components in Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina, and Texas should implement the recommendations as soon as feasible, but not later than 4 weeks after the guidance issue date; and (3) blood establishments that collect Whole Blood and blood components in all other States and territories should implement the recommendations as soon as feasible, but not later than 12 weeks after the date of the issuance of this guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate. The guidance represents the current thinking of FDA on "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100(b) and 606.160(b)(1) have been approved under OMB control number 0910–0795; and the collections of information in 21 CFR 606.122 and 630.30 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20914 Filed 8–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

NAME: National Advisory Committee on Rural Health and Human Services.

DATES AND TIMES:

September 14, 2016, 8:30 a.m.–5:00 p.m. MT
September 15, 2016, 8:30 a.m.–5:15 p.m. MT
September 16, 2016, 8:30 a.m.–11:00 a.m. MT

PLACE:

Albuquerque Marriott, 2101 Louisiana Boulevard NE., Albuquerque, New Mexico 87110, (505) 881–6800.

STATUS: The meeting will be open to the public.

PURPOSE: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

AGENDA: The meeting on Wednesday, September 14, will be called to order at 8:30 a.m. by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The Committee will examine the issue of social determinants of health in rural areas. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will break into subcommittees and depart for site visits Thursday morning, September 15, at approximately 8:30 a.m. Subcommittees will visit the Presbyterian Medical Services Cuba Health Center in Cuba, New Mexico; the Laguna Pueblo, a federally recognized Native American tribe of the Pueblo people in Laguna, New Mexico; and the Guadalupe County Hospital in Santa Rosa, New Mexico. The day will conclude at the Albuquerque Marriott with the period of public comment at approximately 5:15 p.m.

On Friday, September 16, at 8:30 a.m., the Committee will meet at the Albuquerque Marriott to summarize key findings from the site visits and develop a work plan for the next quarter.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Administrative Coordinator, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, 17W41D, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Pierre Joseph at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945–0897 or by email at *PJoseph@hrsa.gov.* Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above at least 10 days prior to the meeting. The Committee meeting agenda will be posted on the Committee's Web site at *http://www.hrsa.gov/advisorycommittees/rural/.*

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–20911 Filed 8–30–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 20, 2016.

Open: 9:00 a.m. to 1:00 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, *jnoronha@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml.*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 24, 2016.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20878 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Integrative Health.

Date: October 14, 2016.

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Open: 10:15 a.m. to 3:30 p.m.

Agenda: A report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892–5475, (301) 594–2014, *goldrosm@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://nccih.nih.gov/about/naccih/*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: August 25, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20877 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences.

Date: September 28–29, 2016.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: Martha L. Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology A Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, Bethesda, MD 20892, (301) 435–2409, *grossmanrs@mail.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology B Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Eileen W. Bradley, DSC, IRG Chief, Surgical Sciences Biomedical Imaging and Bioengineering, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–14–228: Science Education Award Program (SEPA) Grants.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Medical Imaging Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Arlington Pentagon City, 550 Army Navy Drive, Arlington, VA.

Contact Person: Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Sensorimotor Integration Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: September 29, 2016.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group;

Clinical, Integrative and Molecular Gastroenterology Study Section.

Date: September 29, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC 7850, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: September 29, 2016–September 29, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

Date: September 29–30, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: September 29–30, 2016.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Fairmont Hotel, 2401 M Street NW., Washington, DC 20037.

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Molecular Imaging and Probe Development.

Date: September 29–30, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–15–279 Strategies to Increase Delivery of Guideline-Based Care to Populations with Health Disparities.

Date: September 29, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jessica Bellinger, Ph.D., Center for Scientific of Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, *bellingerjd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 14–143: Establishing Behavioral and Social Measures for Causal Pathway Research in Dental, Oral and Craniofacial Health.

Date: September 29, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tasmeen Weik, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, *weikts@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 25, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20876 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: October 18–19, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DDK–C Conflicts.

Date: October 18–19, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK–DP3 Telephone SEP.

Date: October 19, 2016.

Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–16–020–NIDDK Diabetes Research Centers (P30).
Date: October 20, 2016.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD 20814.
Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Parent R01 Applications Review Meeting.
Date: October 26, 2016.
Time: 1:00 p.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301–496–9010, *hoffertj@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 25, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20997 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.
Date: September 27–28, 2016.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.
Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Pathobiology of Kidney Disease Study Section.
Date: September 28–29, 2016.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Fisherman's Wharf Hotel, 2500 Mason Street, San Francisco, CA 94133.
Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, *sahaia@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.
Date: September 28–29, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.
Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.
Date: September 28–29, 2016.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.
Contact Person: Kathryn Kalasinsky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158 MSC 7806, Bethesda, MD 20892, 301–402–1074, *kalasinskyks@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 25, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20994 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.
Date: September 22, 2016.
Time: 11:00 a.m. to 12:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies.
Date: September 27, 2016.
Time: 2:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8886, *sanoviche@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney, Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 25, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21000 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Prevention and Therapy.

Date: September 21, 2016.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Syed M. Quadri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301–435–1211, *quadris@csr.nih.gov*.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: September 26–27, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 W. Kinzie St., Chicago, IL 60654.

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, *howardz@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR15–306: Lymphatics in Health and Disease in the Digestive System, Kidney and Urinary Tract.

Date: September 28, 2016.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, NINDS/NIH, Scientific Review Branch, 6001 Executive Blvd., Bethesda, MD 20892, *jianxinh@mail.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Development—2 Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC, Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurotransporters, Receptors, and Calcium Signaling Study Section.

Date: September 29–30, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street NW., Washington, DC 20037.

Contact Person: Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Development and Application of PET and SPECT Imaging Ligands as Biomarkers for Drug Discovery and for Pathophysiological Studies of CNS Disorders (R21).

Date: September 30, 2016

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival.

Date: September 30, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Pilot Clinical Urology Studies.

Date: September 30, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301–435–1501, *morrisr@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Addiction Risks and Mechanisms Study Section.

Date: October 3–4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel San Diego, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: October 3, 2016.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.

Date: October 3–4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genomics, Computational Biology and Technology Study Section.

Date: October 4–5, 2016.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Baishali Maskeri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–2864, *maskerib@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 26, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20996 Filed 8–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N03A, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.;

MedExpress/National Laboratory Center)
LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244
MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515
One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7
Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840
Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370 (Formerly: SmithKline Beecham Clinical Laboratories)
Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159
Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027
STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438
US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Charles LoDico,
Chemist.

[FR Doc. 2016–20936 Filed 8–30–16; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0111]

Agency Information Collection Activities: Arrival and Departure Record (Forms I–94 and I–94W) and Electronic System for Travel Authorization

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; revision of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: CBP Form I–94 (Arrival/Departure Record), CBP Form I–94W (Nonimmigrant Visa Waiver Arrival/Departure), and the Electronic System for Travel Authorization (ESTA). This is a proposed extension and revision of an information collection that was previously approved. CBP is proposing that this information collection be extended with a revision to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before September 30, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or via email (*CBP_PRA@cbp.dhs.gov*). Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/*. For additional help: *https://help.cbp.gov/app/home/search/1*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (81 FR 40892) on June 23, 2016, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/Departure, and Electronic System for Travel Authorization (ESTA).

OMB Number: 1651–0111.

Form Numbers: I–94 and I–94W.

Abstract

Background

CBP Forms I–94 (Arrival/Departure Record) and I–94W (Nonimmigrant Visa Waiver Arrival/Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by aliens and are used to collect information on citizenship, residency, passport, and contact information. The data elements collected on these forms enable DHS to perform its mission related to the screening of alien visitors for potential risks to national security and the determination of admissibility to the United States. ESTA applies to aliens seeking to travel to the United States under the Visa Waiver Program (VWP) and requires that VWP travelers provide information electronically to CBP before embarking on travel to the United States without a visa. Travelers who are entering the United States under the VWP in the air or sea environment and who have a travel authorization obtained through ESTA are not required to complete the paper Form I–94W.

Pursuant to an interim final rule published on March 27, 2013 in the **Federal Register** (78 FR 18457) related to Form I–94, CBP has partially automated the Form I–94 process. CBP now gathers data previously collected on the paper Form I–94 from existing automated sources in lieu of requiring passengers arriving by air or sea to submit a paper I–94 upon arrival. Passengers can access and print their electronic I–94 via the Web site at *www.cbp.gov/I94.*

ESTA can be accessed at: *https://esta.cbp.dhs.gov.* Samples of CBP Forms I–94 and I–94W can be viewed at: *http://www.cbp.gov/document/forms/form-i-94-arrivaldeparture-record* and *http://www.cbp.gov/document/forms/form-i-94w-visa-waiver-arrivaldeparture-record.*

Recent Changes

On December 18, 2015, the President signed into law the Visa Waiver Program Improvement and Terrorist Travel Prevention Act of 2015 as part of the Consolidated Appropriations Act of 2016. To meet the requirements of this new Act, DHS strengthened the security of the VWP by enhancing the ESTA application and Form I–94W. In two recent emergency submissions under the Paperwork Reduction Act, additional questions were added to ESTA and to Form I–94W that request information from applicants about countries to which they have traveled on or after March 1, 2011; countries of which they are citizens/nationals; countries for which they hold passports; and Global Entry Numbers.

Proposed Changes

DHS proposes to add the following question to ESTA and to Form I–94W: "Please enter information associated with your online presence—Provider/Platform—Social media identifier." It will be an optional data field to request social media identifiers to be used by highly trained CBP personnel for vetting purposes, and applicant contact information. Collecting social media identifiers will enhance the existing vetting process and provide DHS greater clarity and visibility to possible nefarious activity and connections by providing an additional selector which analysts and investigators may use to better assess ESTA applications. Social media information may be used to validate information provided in the ESTA application, such as countries visited, purpose of travel, etc. If an applicant chooses not to fill out or answer questions regarding social media, the ESTA application can still be successfully submitted. If an applicant chooses to answer this question, DHS will have visibility of the publicly available information on those platforms, consistent with the privacy settings the applicant has set on the platforms.

Current Actions: This submission is being made to extend the expiration date with a change to the information collected as a result of adding a question about social media to ESTA and to Form I–94W, as described in the Abstract section of this document. There are no changes to the burden hours or to the information collected on Form I–94, or the I–94 Web site.

Type of Review: Revision.

Affected Public: Individuals, Carriers, and the Travel and Tourism Industry.

Form I–94 (Arrival and Departure Record)

Estimated Number of Respondents: 4,387,550.

Estimated Time per Response: 8 minutes.

Estimated Burden Hours: 583,544.

Estimated Annual Cost to Public: $26,325,300.

I–94 Web Site

Estimated Number of Respondents: 3,858,782.

Estimated Time per Response: 4 minutes.

Estimated Annual Burden Hours: 254,679.

Form I–94W (Nonimmigrant Visa Waiver Arrival/Departure)

Estimated Number of Respondents: 941,291.

Estimated Time per Response: 16 minutes.

Estimated Annual Burden Hours: 251,325.

Estimated Annual Cost to the Public: $5,647,746.

Electronic System for Travel Authorization (ESTA)

Estimated Number of Respondents: 23,010,000.

Estimated Time per Response: 23 minutes.

Estimated Total Annual Burden Hours: 8,812,830.

Estimated Annual Cost to the Public: $265,020,000.

Dated: August 26, 2016.

Seth Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2016–20929 Filed 8–30–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–23]

60-Day Notice of Proposed Information Collection: FHA-Application for Insurance of Advance of Mortgage Proceeds

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: Comments Due Date: October 31, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Acting Director, Office of Multifamily Housing Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Daniel J. Sullivan, at Daniel.J.Sullivan@*hud.gov* or telephone 202–402–1142. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: FHA-Application for Insurance of Advance of Mortgage Proceeds.

OMB Approval Number: 2502–0097.

Type of Request: Extension of a currently approved collection.

Form Number: HUD–92403.

Description of the need for the information and proposed use: To indicate to the mortgagee amounts approved for advance and mortgage insurance.

Respondents (i.e. affected public): Business or other for profit.

Estimated Number of Respondents: 873.

Estimated Number of Responses: 26,190.

Frequency of Response: As needed.

Average Hours per Response: 2 hours.

Total Estimated Burden: 52,380.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 24, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing—Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–20953 Filed 8–30–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–21]

60-Day Notice of Proposed Information Collection: FHA Adjustable Rate Mortgages (ARMS)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 31, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Kevin Stevens, 451 7th Street SW., Washington, DC 20410; email Kevin L. *Stevens@hud.gov;* or telephone 202–402–2673. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: FHA Adjustable Rate Mortgages.

OMB Approval Number: 2502–0322.

Type of Request: Extension of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Housing and Urban-Rural Recovery Act of 1983 amended the National Housing Act to permit FHA to insure adjustable rate mortgages (ARMS). The term of all ARMS insured by HUD–FHA is required to be fully disclosed as part of the loan approval process. Additionally, an annual disclosure is required to reflect the adjustment to the interest rate and monthly mortgage amount. Lenders must electronically indicate that the mortgage to be insured is an ARM and the term or type of the ARM.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 2,535.

Estimated Number of Responses: 164,447.

Frequency of Response: On Occasion.

Average Hours per Response: .05.

Total Estimated Burdens: 822 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Date: August 19, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–20954 Filed 8–30–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5915–N–08]

Notice of Proposed Information Collection for Public Comment on the 2017 American Housing Survey

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 31, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Anna Guido at *Anna.Guido@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: HUD will submit the proposed information collection package to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

A. Overview of Information Collection

Title of Information Collection: 2017 American Housing Survey.

OMB Control Number: 2528–0017.

Description of the need for the information and proposed use: The purpose of the American Housing Survey (AHS) is to supply the public with detailed and timely information about housing quality, housing costs, and neighborhood assets, in support of effective housing policy, programs, and markets. Title 12, United States Code, Sections 1701Z–1, 1701Z–2(g), and 1710Z–10a mandates the collection of this information.

Like the previous surveys, the 2017 AHS will collect "core" data on subjects, such as the amount and types of changes in the housing inventory, the physical condition of the housing inventory, the characteristics of the occupants, housing costs for owners and renters, the persons eligible for and beneficiaries of assisted housing, remodeling and repair frequency, reasons for moving, the number and characteristics of vacancies, and characteristics of resident's neighborhood.

In addition to the "core" data, HUD plans to collect "topical" data on disaster and emergency preparedness, how people commute to work and commuting costs, the causes and effects of evictions, and recent delinquent payments and notices for mortgage, rent, or utility bills.

The AHS national longitudinal sample consists of approximately 92,000 housing units, and includes oversample from the 15 largest metropolitan areas, approximately 5,250 HUD-assisted housing units, and approximately 6,000 "bridge sample" housing units. The bridge sample will allow for estimation of longitudinal changes between 2013, 2015, when the AHS introduced a new sample, and 2017. The bridge sample will also facilitate analyses of the impact of survey design changes on 2017 AHS estimates. In addition to the national longitudinal sample, HUD plans to conduct 15 metropolitan area samples, each with approximately 3,000 housing units (for a total 45,000 metropolitan area housing units).

To help reduce respondent burden on households in the longitudinal sample, the 2017 AHS will make use of dependent interviewing techniques, which will decrease the number of questions asked.

Policy analysts, program managers, budget analysts, and Congressional staff use AHS data to advise executive and legislative branches about housing conditions and the suitability of public policy initiatives. Academic researchers and private organizations also use AHS data in efforts of specific interest and concern to their respective communities.

HUD needs the AHS data for two important uses.

1. With the data, policy analysts can monitor the interaction among housing needs, demand and supply, as well as changes in housing conditions and costs, to aid in the development of housing policies and the design of housing programs appropriate for different target groups, such as first-time home buyers and the elderly.

2. With the data, HUD can evaluate, monitor, and design HUD programs to improve efficiency and effectiveness.

Members of affected public: Households.

Estimated Number of Respondents: 137,000.

Estimated Time per Response: 40 minutes.

Frequency of Response: One time every two years.

Estimated Total Annual Burden Hours: 91,333.

Estimated Total Annual Cost: The only cost to respondents is that of their time. The total estimated cost is $67,600,000.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 9(a), and Title 12, U.S.C., Section 1701z–1 *et seq.*

B. Solicitation of Public Comment

This notice solicits comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 17, 2016.

Katherine M. O'Regan,

Assistant Secretary, Office of Policy Development and Research.

[FR Doc. 2016–20956 Filed 8–30–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X.LLWO320000.L13200000.PP0000]

Renewal of Approved Information Collection; OMB Control No. 1004–0073

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information that enables the BLM to manage Federal coal resources in accordance with applicable statutes. The OMB previously approved this information collection activity, and assigned it control number 1004–0073.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before September 30, 2016.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0073), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: To Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate "Attn: 1004–0073" regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Bill Radden-Lesage, at 202–912–7116. Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Mr. Radden-Lesage. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on March 30, 2016 (81 FR 17732), and the comment period ended May 31, 2016. The BLM received one comment. The comment did not address, and was not germane to, this information collection. It consisted of a general invective against the government and the BLM. Therefore, the BLM has no response to the comment. The BLM now invites comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–0073 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information pertains to this request:

Title: Coal Management (43 CFR parts 3400 through 3480).

OMB Control Number: 1004–0073.

Summary: This collection enables the BLM to learn the extent and qualities of Federal coal resources; evaluate the environmental impacts of coal leasing and development; determine the qualifications of prospective lessees to acquire and hold Federal coal leases; and ensure lessee compliance with applicable statutes, regulations, and lease terms and conditions.

Frequency of Collection: On occasion.

Forms:

- Form 3440–1, Application and License to Mine Coal (Free Use); and
- Form 3400–12, Coal Lease.

Description of Respondents:

- Applicants for, and holders of, coal exploration licenses;
- Applicants/bidders for, and holders of, coal leases;
- Applicants for, and holders of, licenses to mine coal; and
- Surface owners and State and tribal governments whose lands overlie coal deposits.

Estimated Annual Responses: 1,017.

Estimated Annual Burden Hours: 19,897.

Estimated Annual Non-Hour Burdens: $943,153 in document processing fees.

Jean Sonneman,

Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 2016–21080 Filed 8–29–16; 4:15 pm]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO320000 L13300000.FW0000 013X]

Renewal of Approved Information Collection; OMB Control No. 1004–0001

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information that enables the BLM to collect information from applicants for free use permits for vegetative or mineral material. The Office of Management and Budget (OMB) has assigned control number 1004–0001 to this information collection.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before September 30, 2016.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0001), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate "Attn: 1004–0001" regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Mike Bechdolt, at 202–912–7234 (vegetative material); or George Brown, at 202–912–7118 (mineral material). Persons who use a telecommunication device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, to leave a message for Mr. Brown or Mr. Bechdolt. You may also review the information collection request online at *http://www.reginfo.gov/public/.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on March 30, 2016 (81 FR 17732), and the comment period ended May 31, 2016. The BLM received one comment. The comment did not address, and was not germane to, this information collection. Therefore, we have not revised the collection of information in response to the comment.

The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–0001 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information pertains to this request:

Title: Free Use Application and Permit for Vegetative or Mineral Materials (43 CFR parts 3600, 3620, and 5510).

OMB Control Number: 1004–0001.

Summary: The Bureau of Land Management (BLM) collects information from respondents for free use permits for vegetative or mineral materials in order to: (1) Determine whether the applicant is eligible for free use, (2) Determine whether the vegetative or mineral materials at issue qualify for free use; (3) Determine whether free use is consistent with pertinent land use plans and authorities; and (4) Monitor the authorized removal and uses of vegetative and mineral materials to ensure sustainable resource management and verify that the actual use is consistent with the authorization. The BLM seeks approval to continue to use one combined application and permit form for vegetative materials, and begin using two different forms for mineral materials (one for applications, and one for permits).

Frequency of Collection: On occasion.

Forms:

- 3604–1a, Free Use Permit Application for Mineral Materials;
- 3604–1b, Free Use Permit for Mineral Materials; and
- 5510–1, Free Use Application and Permit for Vegetative Materials.

Description of Respondents: Individuals seeking authorization for free use of mineral or vegetative materials.

Estimated Annual Responses: 403.

Estimated Annual Burden Hours: 241.

Estimated Annual Non-Hour Costs: None.

The estimated annual burdens of this collection are itemized below:

Type of response A.	Number of responses B.	Time per response (minutes) C.	Number of hours (Column B × Column C) D.
Form 5510–1 Free Use Application and Permit for Vegetative Material (Federal, State, or Local Governments)	83	30	42

Type of response A.	Number of responses B.	Time per response (minutes) C.	Number of hours (Column B × Column C) D.
Form 5510–1 Free Use Application and Permit for Vegetative Material (Mining Claimants and Nonprofit Organizations)	167	30	84
Forms 3604–1a and 3604–1b Free Use Application and Permit for Mineral Material (Federal, State, or Local Governments)	150	45	113
Forms 3604–1a and 3604–1b Free Use Application and Permit for Mineral Material (Nonprofit Organizations)	3	45	2
Totals	403	....	241

Jean Sonneman,

Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 2016–20907 Filed 8–30–16; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM910000.L13140000.XP0000.16X]

2016 Second Call for Nominations for Certain New Mexico Resource Advisory Councils

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to reopen the request for public nominations for certain New Mexico Bureau of Land Management (BLM) Resource Advisory Councils (RAC) that have member terms expiring this year. These RACs provide advice and recommendations to the BLM on land use planning and management of the National System of Public Lands within their geographic areas. The RACs covered by this request for nominations are identified below. The BLM will accept public nominations for 30 days after the publication of this notice.

DATES: All nominations must be received no later than September 30, 2016.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for the address of BLM New Mexico Offices accepting nominations.

FOR FURTHER INFORMATION CONTACT: Allison Sandoval, U.S. Department of the Interior, Bureau of Land Management, New Mexico State Office, 301 Dinosaur Trail, Santa Fe, NM 87502–0115; 505–954- 2019.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM. Section 309 of FLPMA (43 U.S.C. 1739) directs the Secretary to establish 10- to 15-member citizen-based advisory councils that are consistent with the Federal Advisory Committee Act (FACA). As required by FACA, RAC membership must be balanced and representative of the various interests concerned with the management of the public lands. The rules governing RACs are found at 43 CFR subpart 1784 and include the following three membership categories:

Category One—Holders of Federal grazing permits or leases; representatives of energy and mineral development; representatives of the commercial timber industry; representatives of interests associated with transportation or rights-of-way; or representatives of developed outdoor recreation, off-highway vehicle use, and commercial recreation;

Category Two—Representatives of nationally or regionally recognized environmental organizations; archaeological and historic organizations; dispersed recreation activities; or nationally or regionally recognized wild horse and burro organizations; and

Category Three—Persons who hold State, county, or local elected office; employees of a State agency responsible for management of natural resources, land or water; representatives of Indian tribes within or adjacent to the area for which the council is organized; persons who are employed as academicians in natural resource management or natural sciences; or representatives of the affected public-at-large.

Those who have already submitted a nomination in response to the first call for nominations (published in the **Federal Register** on March 18, 2016, 81 FR 14879) do not need to resubmit. All nominations from the first and second calls will be considered together during the review process. Individuals may nominate themselves or others. Nominees must be residents of the State of New Mexico. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographical area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making. Individuals who are Federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, or councils in an individual capacity. The term "individual capacity" refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest. The following must accompany all nominations for the RACs:

- Letters of reference from represented interests or organizations;
- A completed Resource Advisory Council application; and
- Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, the BLM New Mexico State Office will issue press releases providing additional information for submitting nominations, with specifics about the number and categories of member positions available for each RAC.

Nominations and completed applications for RACs should be sent to the appropriate BLM offices listed below:

Albuquerque District RAC: Carlos Coontz, Socorro Field Office, BLM, 901 South Highway 85, Socorro, NM 87801, (575) 838–1263.

Farmington District RAC: Tamara Faust, Farmington District Office, BLM, 6251 College Boulevard, Farmington, NM 87402, (505) 564–7762.

Authority: 43 CFR 1784.4–1

Sally R. Butts,

Acting Deputy State Director, Lands and Resources.

[FR Doc. 2016–20942 Filed 8–30–16; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A0067F 167S180110; S2D2D SS08011000 SX066A00 33F 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0113

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to request approval for the collection of information for General Reclamation Requirements.

DATES: Comments on the proposed information collection must be received by October 31, 2016, to be assured of consideration.

ADDRESSES: Mail comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or via email at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies the information collection that OSMRE will be submitting to OMB for extension. This collection is contained in 30 CFR part 874.

OSM has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on reestimates of burden or number of respondents. OSMRE will request a 3-year term of approval for this information collection activity.

Comments are invited on: (1) the need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSMRE's submission of the information collection request to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment–including your personal identifying information–may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

This notice provides the public with 60 days in which to comment on the following information collection activity:

Title: 30 CFR part 874—General Reclamation Requirements.

OMB Control Number: 1029–0113.

Summary: Part 874 establishes land and water eligibility requirements, reclamation objectives and priorities and reclamation contractor responsibility. 30 CFR 874.17 requires consultation between the AML agency and the appropriate Title V regulatory authority on the likelihood of removing the coal under a Title V permit and concurrences between the AML agency and the appropriate Title V regulatory authority on the AML project boundary and the amount of coal that would be extracted under the AML reclamation project.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: 17 State regulatory authorities and Indian tribes.

Total Annual Responses: 17.

Total Annual Burden Hours: 1,411.

Dated: *August 25, 2016.*

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2016–20937 Filed 8–30–16; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–794]

Certain Electronic Devices, Including Wireless Communication Devices, Portable Music and Data Processing Devices, and Tablet Computers Sanction for Breaches of Administrative Protective Order

AGENCY: U.S. International Trade Commission.

ACTION: Sanction for breaches of Commission administrative protective order.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has imposed a sanction for the breach of the administrative protective order ("APO") issued in this investigation. The Commission determined that the law firm of Quinn Emanuel Urquhart & Sullivan, LLP ("Quinn Emanuel") breached the APO by failing to adequately control access to confidential business information ("CBI") in the investigation and litigation in the U.S. District for the Northern District of California. As a result, Quinn Emanuel attorneys and employees of complainants Samsung Telecommunications America LLC and Samsung Electronics Co., Ltd. (collectively, "Samsung") improperly disclosed CBI to more than 140 unauthorized persons over a fourteen-month period. Quinn Emanuel is being publicly reprimanded for pervasive problems at the firm in safeguarding CBI.

FOR FURTHER INFORMATION CONTACT: Carol McCue Verratti, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3088. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal at (202) 205–1810. General information concerning the Commission can also be obtained by accessing its Internet server (*https://www.usitc.gov*).

SUPPLEMENTARY INFORMATION: Several Quinn Emanuel attorneys inadvertently disclosed CBI designated by respondent Apple Inc. as CBI in the investigation and for cross-use in litigation in the U.S. District for the Northern District of California to persons who were not authorized to access CBI under the APO.

A junior associate at Quinn Emanuel failed to fully redact CBI from an expert report prepared for the district court action, and a partner at Quinn Emanuel failed to supervise the junior associate.

Quinn Emanuel attorneys subsequently sent the incompletely redacted expert report to unauthorized persons at Samsung and other law and consulting firms on several occasions. Some of the non-signatory recipients further disseminated the CBI to other non-signatories, including an Italian court. One of the incidents involved a partner at Quinn Emanuel emailing more than 90 Samsung employees with instructions on how to access the incompletely redacted expert report on an FTP site. Another incident involved a second associate who failed to safeguard CBI by improperly confirming the redactions. In another incident, the same junior associate who made the original redactions discovered that an incompletely redacted report had been inadvertently disclosed to a Samsung employee and alerted the second associate and a supervising partner. Although the Samsung employee deleted the report without viewing the CBI, the second associate later sent a revised version that still contained CBI. No one at Quinn Emanuel notified Apple or the Commission of the disclosure at the time. No other efforts were made to investigate whether other disclosures had been made so as to prevent further disclosures. As a result, the unauthorized disclosures continued.

In connection with the investigation before the Commission, a mid-level associate at Quinn Emanuel failed to redact the same CBI from an outline for a brief on remedy and the public interest. Quinn Emanuel attorneys subsequently sent versions of the outline and the public interest brief containing CBI to unauthorized persons at Samsung and other law firms on several occasions. A partner at Quinn Emanuel discovered one such disclosure, but did not notify Apple or the Commission at the time because he had acted promptly after the discovery to prevent unauthorized persons from viewing CBI.

A third party filed a motion for a protective order in the district court action, alleging that Samsung had obtained CBI. Quinn Emanuel notified the Commission of certain of the disclosures a month later, and two weeks after it had notified the third party of the same disclosures.

The Commission considered several aggravating factors, including the viewing of CBI by unauthorized persons; the discovery of the breaches by a third party; Quinn Emanuel's failure and delay in reporting to the Commission the disclosures when they were discovered; the lengthy period of time in which CBI was unprotected; multiple breaches by Quinn Emanuel attorneys in the same investigation; and multiple breaches by Quinn Emanuel attorneys in a two-year period. The Commission also considered several mitigating factors, including the inadvertent nature of the breaches; Quinn Emanuel's recent implementation of a firm-wide policy to help prevent unauthorized disclosures; Quinn Emanuel's prompt and strenuous efforts to investigate, cure, and prevent further breaches; and the fact that a federal district court has already sanctioned the disclosures and conduct underlying the breaches relating to the expert report.

Although Quinn Emanuel had procedures to prevent unauthorized disclosures, the firm did not ensure that attorneys complied with those procedures and made unilateral decisions regarding the APO's scope and requirements. The large number and the vast extent of the unauthorized disclosures show that the failure to safeguard CBI was a pervasive problem at Quinn Emanuel.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 25, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–20869 Filed 8–30–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[Docket No. ATF 2015R–15]

Electronic Collection and Transfer of Import Information: Cessation of PGA Message Set Pilot Program

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: Notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) announces cessation of the pilot program that tested the transfer of data between the Participating Government Agency (PGA) Message Set in the Automated Commercial Environment (ACE) and ATF's Web-based data analytics system. ACE is the Web-based portal for the collection and use of international trade data maintained by U.S. Customs and Border Protection (CBP). The PGA Message Set is the data related to merchandise regulated by an agency, such as ATF, that CBP will receive electronically from importers for its use as well as for the PGA's use. The data enables ATF to determine the actual items imported. Although this notice announces the cessation of the pilot program, the mandatory filing date for filing entries in ACE has yet to be determined.

DATES: This notice is effective on August 31, 2016.

FOR FURTHER INFORMATION CONTACT: William E. Majors, Chief, Firearms and Explosives Imports Branch, Firearms and Explosives Services Division, Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms and Explosives; U.S. Department of Justice; 244 Needy Road, Martinsburg, WV 25401; telephone (304) 616–4589, fax: (304) 616–4551, or email: *William.Majors@atf.gov.*

SUPPLEMENTARY INFORMATION: ATF participated in a voluntary CBP pilot program of the International Trade Data System (ITDS) involving the use of the PGA Message Set in ACE. See 80 FR 45548 (July 30, 2015). The pilot allowed importers to submit required data to CBP through ACE for the purposes of obtaining CBP release and receipt. CBP validated that information electronically, and electronically transmitted entry and release information to ATF for purposes of satisfying certification requirements. The pilot program confirmed the efficiency and effectiveness of digitizing traditional, manual paperwork. While the pilot has been suspended, the mandatory filing date for filing entries in ACE has yet to be determined.

Importers should be aware that no changes have been made to the requirement that importers submit their copy of the Form 6A (with Sections I and III completed) to ATF within 15 days of release from CBP custody.

Thomas E. Brandon,

ATF Deputy Director.

[FR Doc. 2016–20939 Filed 8–30–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0008]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application and Permit for Permanent Exportation of Firearms (National Firearms Act) ATF F 9 (5320.9)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 31, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kenneth Mason, Firearms and Explosives Services Specialist, National Firearms Act Branch, 244 Needy Road, Martinsburg, WV 25405, at email: *nfaombcomments@atf.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form OMB 83–I):* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application and Permit for Permanent Exportation of Firearms (National Firearms Act).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF F 9 (5320.9).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): Individuals or households.

Abstract: ATF Form 9 (5320.9) is typically used by a Federal firearms licensee who has paid the special (occupational) tax to deal, manufacture or import NFA firearms. The form must be filed (in quadruplicate) for approval to permanently export NFA firearms registered in the National Firearms Registration and Transfer Record. Once authorization has been granted, one copy is retained by ATF and the remaining copies returned to the exporter to establish that the exportation took place and claim relief from liability for the transfer tax.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,339 respondents will take 18 minutes to respond.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 401 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: August 25, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–20915 Filed 8–30–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0096]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Environmental Information (ATF F 5000.29)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** 81 FR 41595, on June 27, 2016, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until September 30, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Shawn Stevens, ATF Industry Liaison, Federal Explosives Licensing Center, 244 Needy Road, Martinsburg, WV 25405, at telephone: 1–877–283–3352. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Environmental Information

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5000.29.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other: None.

Abstract: The information will help ATF identify any waste product(s) generated as a result of the operations by the applicant and the disposal of the products. The information will help determine if there is any adverse impact on the environment.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 680 respondents will take 30 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 340 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: August 25, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–20917 Filed 8–30–16; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On August 19, 2016, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Massachusetts in the lawsuit entitled *United States* v. *City of Haverhill*, Civil Action No. 16–cv–11698–IT.

In the Complaint, the United States, on behalf of the U.S. Environmental Protection Agency (EPA), alleges that the defendant City of Haverhill violated the Clean Water Act (CWA), 33 U.S.C. 1251, *et seq.*, and applicable regulations relating to the City's failure to comply with its National Pollutant Discharge Elimination System permit and its Small Municipal Separate Storm Sewer System permit under the CWA. The proposed Consent Decree requires the City to pay a civil penalty of $125,000 and undertake measures to achieve compliance with the CWA and applicable regulations. In addition, as a Supplemental Environmental Project the City will restore a riverbank area near Riverside Park on the Merrimack River.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *City of Haverhill*, D.J. Ref. No. 90–5–1–1–10992. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $20.25 (25 cents per page reproduction cost), not including Appendices, payable to the United States Treasury.

Robert E. Maher, Jr.,

Assistant Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 2016–20947 Filed 8–30–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Certificate of Electrical Training and Applications for Mine Safety and Health Administration Approved Tests and State Tests Administered as Part of a Mine Safety and Health Administration Approved Program

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, "Certificate of Electrical Training and Applications for Mine Safety and Health Administration Approved Tests and State Tests Administered as Part of a Mine Safety and Health Administration Approved Program," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 30, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201604-1219-003* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Certificate of Electrical Training and Applications for Mine Safety and Health Administration Approved Tests and State Tests Administered as Part of a Mine Safety and Health Administration Approved Program information collection. Instructors use MSHA Form 5000–1, "Certificate of Electrical Training," to report the qualification of persons satisfactorily completing a coal mine electrical training program course to the MSHA. The Agency is also requesting approval for applications for MSHA approved tests and for State tests that are administered as part of an MSHA-approved State program. Federal Mine Safety and Health Act of 1977 sections 101(a) and 103(h) authorize this information collection. *See* 30 U.S.C 811(a) and 813(h).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1219–0001.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 20, 2016 (81 FR 31968).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1219–0001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Certificate of Electrical Training and Applications for Mine Safety and Health Administration Approved Tests and State Tests Administered as Part of a Mine Safety and Health Administration Approved Program.

OMB Control Number: 1219–0001.

Affected Public: State, Local, and Tribal Governments; Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 289.

Total Estimated Number of Responses: 1,414.

Total Estimated Annual Time Burden: 599 hours.

Total Estimated Annual Other Costs Burden: $274.

Dated: August 25, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–20940 Filed 8–30–16; 8:45 am]

BILLING CODE 4510–43–P

MERIT SYSTEMS PROTECTION BOARD

Membership of the Merit Systems Protection Board's Performance Review Board

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: Notice is hereby given of the members of the Merit Systems Protection Board's Performance Review Board.

DATES: August 31, 2016.

FOR FURTHER INFORMATION CONTACT: Marion Hines at 202–254–4413 or *marion.hines@mspb.gov.*

SUPPLEMENTARY INFORMATION: The Merit Systems Protection Board is publishing the names of the current and new members of the Performance Review Board (PRB) as required by 5 U.S.C. 4314(c)(4). William D. Spencer continues to serve as Chairman of the PRB. Laura M. Albornoz is a new member of the PRB. Susan M. Swafford and William L. Boulden continue to serve as members of the PRB.

William D. Spencer,

Clerk of the Board.

[FR Doc. 2016–20992 Filed 8–30–16; 8:45 am]

BILLING CODE 7400–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–059)]

Annual Invitation for Public Nominations by U.S. Citizens for Service on NASA Federal Advisory Committees

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice.

SUMMARY: NASA announces its annual invitation for public nominations for service on NASA Federal advisory committees. U.S. citizens may submit self-nominations for consideration as potential members of NASA's Federal advisory committees. NASA's Federal advisory committees have member vacancies from time to time throughout the year, and NASA will consider self-nominations to fill such intermittent vacancies. NASA is committed to selecting members to serve on its Federal advisory committees based on their individual expertise, knowledge, experience, and current/past contributions to the relevant subject area.

DATES: The deadline for NASA receipt of all public nominations is September 30, 2016.

FOR FURTHER INFORMATION CONTACT: For any questions, please contact Ms. Marla King, Advisory Committee Specialist, Advisory Committee Management Division, Office of International and Interagency Relations, NASA Headquarters, Washington, DC 20546, (202) 358–1148. To view advisory committee charters and obtain further information on NASA's Federal advisory committees, please visit the NASA Advisory Committee Management Division Web site noted in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION: Self-nominations from interested U.S. citizens must be sent electronically to NASA in letter form, be signed, and must include the name of specific NASA Federal advisory committee of interest for NASA consideration. Self-nomination letters are limited to specifying interest in only one (1) NASA Federal advisory committee per year. The following additional information is required to be attached to each self-nomination letter (*i.e.,* cover letter): (1) Professional resume (one-page maximum); (2) professional biography (one-page maximum). Please submit the self-nomination package as a single package containing cover letter and both required attachments to *hq-nasanoms@mail.nasa.gov.* All public self-nomination packages must be submitted electronically via email to NASA; paper-based documents sent through postal mail (hard-copies) will not be accepted. NOTE: Nomination letters that are noncompliant with the directions above and do not include the two (2) mandatory documents listed will not receive further consideration by NASA. NASA's six (6) currently chartered Federal advisory committees are listed below. The individual charters may be found at the NASA Advisory Committee Management Division's Web site at *http://oiir.hq.nasa.gov/acmd.html:*

- *Aerospace Safety Advisory Panel*—The Aerospace Safety Advisory Panel provides advice and recommendations to the NASA Administrator and the Congress on matters related to safety, and performs such other duties as the NASA Administrator may request.
- *Applied Sciences Advisory Committee*—The Applied Sciences Advisory Committee provides advice and makes recommendations to the Director, Earth Science Division, Science Mission Directorate, NASA Headquarters, on Applied Sciences programs, policies, plans, and priorities.
- *International Space Station (ISS) Advisory Committee*—The ISS Advisory Committee provides advice and recommendations to the NASA Associate Administrator for Human Exploration and Operations Mission Directorate on all aspects related to the safety and operational readiness of the ISS. It addresses additional issues and/or areas of interest identified by the NASA Associate Administrator for Human Exploration and Operations Mission Directorate.
- *International Space Station (ISS) National Laboratory Advisory Committee*—The ISS National Laboratory Advisory Committee monitors, assesses, and makes recommendations to the NASA Administrator regarding effective utilization of the ISS as a national laboratory and platform for research, and such other duties as the NASA Administrator may request.
- *NASA Advisory Council*—The NASA Advisory Council (NAC) provides advice and recommendations to the NASA Administrator on Agency programs, policies, plans, financial controls, and other matters pertinent to the Agency's responsibilities. The NAC consists of the Council and five (5) Committees: Aeronautics; Human Exploration and Operations; Institutional; Science; and Technology, Innovation and Engineering. NOTE: All nominations for the NASA Advisory Council must indicate the specific entity of interest, *i.e.,* either the Council or one of its five (5) Committees.
- *National Space-Based Positioning, Navigation and Timing (PNT) Advisory Board*—The National Space-Based PNT Advisory Board provides advice to the PNT Executive Committee (comprised of nine stakeholder Federal agencies, of which NASA is a member) on U.S. space-based PNT policy, planning, program management, and funding profiles in relation to the current state of national and international space-based PNT services.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–20863 Filed 8–30–16; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0178]

Enhancing Participation in NRC Public Meetings

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed revision to policy statement; request for comments.

SUMMARY: To further clarify and enhance participation in public meetings conducted by the U.S. Nuclear Regulatory Commission (NRC), the NRC is proposing to revise its public meeting policy. The revised policy statement redefines the three categories of public meetings and identifies the level of public participation offered at each type of meeting. The revised policy statement also clarifies notification expectations for meetings that include physical presence in the meeting room and meetings that rely solely on remote access technology such as a teleconferencing. The proposed revisions will improve the consistency of the NRC's public meetings and help participants better prepare for NRC meetings.

DATES: Submit comments by November 14, 2016. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0178. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lance Rakovan, Office of the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2589; email: *Lance.Rakovan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0178 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0178.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0178 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Further Information

The entire text of the proposed revision of the policy statement, "Enhancing Public Participation in NRC Meetings," is available as an attachment to this document.

Dated at Rockville, Maryland, this 24th day of August, 2016.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Attachment—Commission Policy Statement on Staff Meetings Open to the Public

A. Purpose

The Nuclear Regulatory Commission's (NRC) longstanding practice is to provide the public with substantial information on its activities, to conduct business in an open manner, and to balance openness and transparency with the need to exercise regulatory and safety responsibilities without undue administrative burden. The NRC's policy is to open meetings between the agency staff and one or more outside persons to observation and participation to the extent possible. The NRC has had a formal policy regarding open (public) meetings since 1978. The current Commission Policy Statement Enhancing Public Participation in NRC Meetings was issued in 2002 and can be accessed at *http://www.nrc.gov/reading-rm/doc-collections/commission/policy/67fr36920.html.*

This policy establishes three public meeting categories based on the level of participation offered to attendees. The policy provides information such as descriptions of each category, information on how public meetings are announced, post-meeting activities, and applicability and exceptions.

B. Participation in NRC Public Meetings

In order to fulfill the NRC's commitment to openness, the level of participation, purpose, and description for each category of public meeting are described below. When assigning a category to a meeting, NRC staff will consider the objective of the meeting and the extent of known public interest in the topic.

The three meeting categories are based on the level of public participation to be provided at each type of meeting. Thus, some categories may support multiple meeting formats. The label for each category provides an indication of the level of participation meeting attendees can expect.

The NRC is committed to providing an atmosphere of civility and inclusion at its public meetings. All participants are expected to follow established ground rules, including those provided in the applicable meeting notice posted on the NRC's public Web site, to support this atmosphere of civility and inclusion regardless of personal viewpoints. If the actions of one or more participants significantly impact this atmosphere, and therefore other participants' ability to observe or participate in a meeting, the NRC staff shall take appropriate actions to restore a more respectful environment, including ending a meeting early if necessary.

Observation Meeting

Meeting Purpose—The purpose of this type of meeting is for the NRC to meet with representatives from one or more groups in an open and transparent manner to discuss regulatory and technical matters. The meeting will inform the public by providing information to help them understand the applicable regulatory issues and NRC actions.

Level of Participation—Other attendees besides the representatives noted above are invited to observe the meeting and discuss regulatory issues with NRC representatives at a designated point or points identified on the agenda. This does not preclude the licensee from responding to questions if they choose to do so.

Description—Meetings in this category include the NRC meeting with one or more industry groups, licensees, vendors, applicants, potential applicants, or non-government organizations, to discuss regulatory issues regarding a specific facility (or facilities), certificates of compliance, licenses, or license applications. This category of meeting could also include the NRC meeting with representatives of task force groups, industry groups, or public interest and citizen groups. The primary discussions are expected to occur between the NRC and representatives of those entities or groups.

The following description will be included in an Observation Meeting notice:

This is a meeting in which attendees will have an opportunity to observe the NRC performing its regulatory function or discussing regulatory issues. Attendees will have an opportunity to ask questions of the NRC staff or make comments about the issues discussed following the business portion of the meeting, but the NRC is not actively soliciting comments on regulatory decisions.

Examples—Meetings of this category may include meetings with licensees (or applicants) to discuss license renewal, amendment or exemption requests; meetings with applicants related to topical report reviews, combined licenses, early site permits, or design certifications; annual public meetings to discuss plant performance as part of the Reactor Oversight Process; renewals, or amendments. Certain inspection exit meetings, such as those for Incident Investigation Teams or Augmented Inspection Teams, are included under this category.

Information Meeting With a Question and Answer Session

Meeting Purpose—The purpose of this type of meeting is for the NRC to share information and discuss applicable regulatory issues and NRC actions with meeting attendees. The meeting will inform the public by providing information to help them understand the applicable regulatory issues and NRC actions through NRC presentations and discussions with NRC staff. These are organized, yet informal opportunities to interact with and ask questions of the NRC staff not associated with a more traditional public meeting format.

Level of Participation—This type of meeting is tailored to inform attendees and allow them to ask questions.

Description—Meetings in this category are held with interested parties, including representatives of non-government organizations, private citizens, or various businesses or industries, to engage them in a discussion of regulatory issues.

The following description will be included in the notice for an Information Meeting with a Question and Answer Session:

The purpose of this meeting is for the NRC staff to meet directly with individuals to provide an opportunity to discuss regulatory and technical issues. Attendees will have an opportunity to ask questions of the NRC staff or make comments about the issues discussed throughout the meeting, however the NRC is not actively soliciting comments towards regulatory decisions at this meeting.

Examples—Meetings of this category may include town hall and roundtable discussions, and open house meetings.

Comment-Gathering Meeting

Meeting Purpose—The purpose of this type of meeting is for the NRC to obtain feedback on regulatory issues and NRC actions. In most cases, the meeting will include a presentation by the NRC to explain the regulatory issue. The feedback received at these meetings is used to support actions such as licensing and rulemaking activities.

Level of Participation—This type of meeting is tailored for attendees to provide opinions, perspectives, and feedback.

Description—This type of meeting would be held with a broad number of interested parties, including representatives of non-government organizations, private citizens, or various businesses or industries, to fully engage them in a discussion of a specific regulatory issue.

The following description will be included in the notification of a Comment-Gathering Meeting:

The purpose of this meeting is for NRC staff to meet directly with individuals to receive comments from participants on specific NRC decisions and actions to ensure that NRC staff understands their views and concerns.

The notice for such meetings should include details as to how comments will be taken at the meeting (*e.g.*, NRC staff taking notes, or creating a transcript of the meeting) and how NRC will use the comments (*e.g.*, to inform NRC discussions, or as official comments related to a formal NRC regulatory decision), as well as to clarify whether participants will need to also submit comments made at the meeting in writing to receive formal consideration.

Examples—Meetings of this category may include town hall and roundtable discussions, environmental impact statement scoping meetings, and workshops.

C. Notice and Access

Although the extent of meeting outreach and preparation by NRC staff can be different for each meeting, certain steps are usually taken. Meeting information will be announced as soon as the NRC staff is reasonably confident that a meeting will be held and firm date, time, and facility arrangements have been made. This will generally occur no fewer than 10 days before a meeting. When a meeting must be scheduled but cannot be announced within the 10-day timeframe, the NRC staff will provide as much advance notice as possible.

Public notice of meetings will be made through the NRC's Public Meetings & Involvement Web page at *http://www.nrc.gov/public-involve.html.* Meeting changes or cancellations will also be announced promptly on this Web page. Individuals who cannot access the NRC's public Web site can contact the NRC's PDR staff via a toll-free number (1–800–397–4209) or by email (*pdr.resource@nrc.gov*) for information on scheduled NRC meetings. Some meetings, specifically meetings with a high level of public interest, may also be noticed in the **Federal Register** or through other means such as a press release, blog post, or advertisement in local newspapers.

Meeting details and materials such as an agenda, names of participants, and background documents will be entered into the NRC's Public Meeting Schedule Web site. A link to the materials as well as the Agencywide Documents Access and Management System (ADAMS) accession number for additional meeting materials such as presentations will, when possible, be provided in the meeting notice on the NRC's public Web site under the "Public Meetings & Involvement" page at *http://www.nrc.gov/public-involve.html.*

Audio teleconferencing and other technologies that allow participation from locations other than a meeting room will be used whenever possible to help ensure widespread involvement in meetings. If information on how to participate remotely in a meeting is not provided in the meeting notice, individuals may request the use of such technology through the meeting contact listed on the meeting notice. Such requests may be granted to the extent budgeted resources are available and technical factors can be accommodated.

D. After-Meeting Activities

The NRC staff will provide answers to questions as appropriate during the public meeting and will inform attendees at the meeting how it plans to address questions that cannot be answered at the meeting. Informal follow-up (telephone or email) may be appropriate. Individuals also have the option of calling, writing, or emailing the NRC staff about particular concerns. NRC staff will provide feedback forms at all public meetings so that comments can be reviewed and offices can track any planned improvements or resulting actions, as appropriate. NRC staff will make meeting summaries publicly available in ADAMS following the meeting.

E. Innovation

The NRC staff will make efforts, as appropriate, to find new and innovative ways to interact with individuals, including exploring varied meeting formats and other ways to incorporate technologies that allow participation from locations other than a meeting room. Experiences with new methods will be shared across the agency for information and consideration by other NRC staff.

F. Applicability and Exceptions

This policy applies to planned, formal encounters between NRC staff members and outside individuals or entities, with an expressed intent of discussing substantive issues directly associated with the NRC's regulatory responsibilities. Such meetings will be designated in advance as public meetings, open for public attendance and categorized in accordance with this policy, subject to the following conditions and exceptions:

1. This policy applies solely to NRC staff-sponsored and conducted meetings with an outside individual or entity. It does not apply to a meeting conducted by an outside individual or entity where an NRC staff member might participate, nor when an NRC employee attends a meeting outside of his or her official capacity.

2. This policy does not apply to meetings between the NRC staff and outside individuals or entities who are:

a. Under contract to the NRC;

b. Acting as an official consultant to the NRC;

c. Acting as an official representative of an agency of the executive, legislative, or judicial branch of the U.S. Government (except on matters where the agency is subject to NRC regulatory oversight);

d. Acting as an official representative of a foreign government or representing an international organization such as the International Atomic Energy Agency; or

e. Acting as an official representative of a State or local government or Tribal official.

3. Meetings between the NRC staff and outside individuals or entities will not be designated as public meetings if the NRC staff determines that the subject matter or information to be discussed in the meeting:

a. Is specifically authorized by an Executive Order to be withheld in the interests of national defense or foreign policy (classified information);

b. Is specifically exempt from public disclosure by statute (*e.g.*, safeguards or proprietary information);

c. Is of a personal nature where such disclosure would constitute a clearly unwarranted invasion of personal privacy;

d. Is related to a planned, ongoing, or completed investigation, or contains information compiled for law enforcement purposes;

e. Could compromise the ongoing reviews and inspections associated with an open allegation;

f. Could result in the inappropriate disclosure and dissemination of preliminary, pre-decisional, or unverified information;

g. Is for general information exchange having no direct, substantive connection to a specific NRC regulatory decision or action; however, should discussions in a closed meeting approach issues that might lead to a specific regulatory decision or action, the NRC staff may advise the meeting attendees that such matters cannot be discussed and propose discussing the issues in a future public meeting; or

h. Indicates that the administrative burden associated with public attendance at the meeting could interfere with the NRC staff's execution of its safety and regulatory responsibilities, such as when the meeting is an integral part of the execution of the NRC inspection program.

4. This policy does not apply to Commission meetings, advisory committee meetings, meetings related to financial assistance or acquisition requirements, or to meetings sponsored by offices that report directly to the Commission (for example, the Office of the General Counsel or the Office

of the Chief Financial Officer). Similarly, it does not apply to "government-to-government" meetings: Meetings between NRC staff and representatives of State governments, including Agreement State representatives, relating to NRC Agreement State activities or to State regulatory actions or to other matters of general interest to the State or to the Commission, as well as meetings between NRC staff and representatives of local or Tribal governments. Also, the policy does not apply to or supersede any existing law, rule or regulation that addresses public attendance at a specific type of meeting. For example, part 7 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Advisory Committees," and 10 CFR part 9, "Public Records," will continue to be applicable to advisory committee meetings and Commission meetings, respectively.

5. This policy does not cover the hearings associated with adjudicatory proceedings under the Commission's Rules of Practice and Procedure set forth in 10 CFR part 2. The term "hearings" relates primarily to Commission adjudicatory proceedings on various types of license applications and licensing actions (*e.g.,* applications for initial issuance of a license, amendment of an existing license, renewal of a license) or to enforcement actions involving the imposition of civil penalties or orders to modify, suspend, or revoke a license or take other appropriate action. Specific requirements regarding participation in and the conduct of adjudicatory proceedings (including the settlement of such proceedings) are provided in the Commission's Rules of Practice and Procedure set forth in 10 CFR part 2. This policy does not cover meetings concerning the settlement of enforcement matters.

6. Certain meetings that would normally be closed under section F.3.a. or F.3.b. above may be opened to cleared members of the public who also have a need-to-know. A cleared member of the public is a person who holds a U.S. Government security clearance or has been granted access to Safeguards Information in accordance with 10 CFR 73.22(b).

7. This policy may be applicable to only part of a meeting. For example, an NRC meeting may have a portion that is open to the public and a portion that is closed to the public due to any of the exceptions listed above. In these cases, this policy statement is applicable to the public portion of the meeting only.

8. This policy is a matter of NRC discretion; the NRC reserves the right to depart from any stated conditions as circumstances may warrant.

G. Contact

The primary point of contact in the agency for general issues related to this policy will be the Deputy Assistant for Operations, Office of the Executive Director for Operations. The Office of Public Affairs is also available to receive questions and suggestions. There are also opportunities for comment on our public participation policies, or on many of our programs through the NRC's Web site under the "Public Meetings & Involvement" page at *http://www.nrc.gov/public-involve.html.*

[FR Doc. 2016–20946 Filed 8–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0211]

Instrumentation and Controls Guidance

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan-final section revision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a final revision to Chapter 7, "Instrumentation and Controls," of NUREG–0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition."

DATES: The effective date of this SRP update is September 30, 2016.

ADDRESSES: Please refer to Docket ID NRC–2015–0211 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0211. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn Lauron, telephone: 301–415–2736; email: *Carolyn.Lauron@nrc.gov* or Mark Notich, telephone: 301–415–3053; email: *Mark.Notich@nrc.gov;* both are staff of the Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On September 16, 2015 (80 FR 55654), the NRC published for public comment the proposed revisions to Chapter 7 of the SRP. The NRC made no changes to the proposed revisions after the consideration of comments received. A summary of the comments and the NRC staff's disposition of the comments are available in a separate document, "Response to Public Comments on Draft SRP Sections in Chapter 7."

The Office of New Reactors and the Office of Nuclear Reactor Regulation are revising these sections from their current versions. Details of specific changes in the proposed revisions are included at the end of each of the proposed sections.

The changes to this SRP chapter reflect current NRC staff's review methods and practices based on lessons learned from the NRC's reviews of design certification and combined license applications completed since the last revision of this chapter.

II. Backfitting and Finality Provisions

Issuance of these revised SRP sections does not constitute backfitting as defined in § 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), "Backfitting," (the Backfit Rule) and is not inconsistent with the issue finality provisions in 10 CFR part 52. The NRC's position is based upon the following considerations:

1. The SRP positions do not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.

The SRP provides guidance to the staff on how to review an application for the NRC's regulatory approval in the form of licensing. Changes in internal staff guidance are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of 10 CFR part 52.

2. The NRC staff has no intention to impose the SRP positions on current licensees and regulatory approvals either now or in the future.

The staff does not intend to impose or apply the positions described in the SRP to existing (already issued) licenses and regulatory approvals. Therefore, the issuance of a final SRP—even if considered guidance that is within the purview of the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP on holders of already issued licenses in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the Backfit Rule or address the criteria for avoiding issue finality as described in the applicable issue finality provision.

3. Backfitting and issue finality do not—with limited exceptions not applicable here—protect current or future applicants.

Applicants and potential applicants are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions under 10 CFR part 52—with certain exclusions discussed in the next paragraph—were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR part 52 license (*e.g.,* an early site permit) and/or NRC regulatory approval (*e.g.,* a design certification rule) with specified issue finality provisions. The staff does not, at this time, intend to impose the positions represented in the SRP in a manner that is inconsistent with any issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must address the criteria for avoiding issue finality as described in the applicable issue finality provision.

III. Congressional Review Act

This action is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Availability of Documents

The documents identified in the following table are available to interested persons.

Document	ADAMS accession No.
Summary of Comments and NRC Staff Disposition of Comments—Response to Public Comments on Draft SRP Sections in Chapter 7	ML16050A366
SRP 7.0, "Instrumentation and Controls—Overview of Review Process," Revision 7	ML16020A049
SRP 7.1, "Instrumentation and Controls—Introduction," Revision 6	ML16020A050
Table 7–1, "Table 7–1 Regulatory Requirements, Acceptance Criteria, and Guidelines for Instrumentation and Control Systems Important to Safety," Revision 6	ML16020A103
SRP 7.2, "Reactor Trip System," Revision 6	ML16020A059
SRP 7.3, "Engineered Safety Features Systems," Revision 6	ML16020A082
SRP 7.4, "Safe Shutdown Systems," Revision 6	ML16020A086
SRP 7.5, "Information Systems Important to Safety," Revision 6	ML16020A088
SRP 7.6, "Interlock Systems Important to Safety," Revision 6	ML16020A092
SRP 7.7, "Control Systems," Revision 6	ML16020A095
SRP 7.8, "Diverse Instrumentation and Control Systems," Revision 6	ML16020A096
SRP 7.9, "Data Communication Systems," Revision 6	ML16020A097
App. 7.0–A, "Review Process for Digital Instrumentation and Control Systems," Revision 6	ML16019A085
App. 7.1–A, "Acceptance Criteria and Guidelines for Instrumentation and Controls Systems Important to Safety," Revision 6	ML16019A088
App. 7.1–B, "Guidance for Evaluation of Conformance to IEEE Std 279," Revision 6	ML16019A091
App. 7.1–C, "Guidance for Evaluation of Conformance to IEEE Std 603," Revision 6	ML16019A107
App. 7.1–D, "Guidance for Evaluation of the Application of IEEE Std 7–4.3.2," Revision 1	ML16019A114
BTP 7–1, "Guidance on Isolation of Low-Pressure Systems from the High-Pressure Reactor Coolant System," Revision 6	ML16019A127
BTP 7–2, "Guidance on Requirements of Motor-Operated Valves in the Emergency Core Cooling System Accumulator Lines," Revision 6	ML16019A299
BTP 7–3, "Guidance on Protection System Trip Point Changes for Operation with Reactor Coolant Pumps Out of Service," Revision 6	ML16019A358
BTP 7–4, "Guidance on Design Criteria for Auxiliary Feedwater Systems," Revision 6	ML16020A028
BTP 7–5, "Guidance on Spurious Withdrawals of Single Control Rods in Pressurized Water Reactors," Revision 6	ML16020A033
BTP 7–6, "Guidance on Design of Instrumentation and Controls Provided to Accomplish Changeover from Injection to Recirculation Mode," Revision 6	ML16011A106
BTP 7–8, "Guidance for Application of Regulatory Guide 1.22," Revision 6	ML16020A044
BTP 7–9, "Guidance on Requirements for Reactor Protection System Anticipatory Trips," Revision 6	ML16011A062
BTP 7–10, "Guidance on Application of Regulatory Guide 1.97," Revision 6	ML16019A169
BTP 7–11, "Guidance on Application and Qualification of Isolation Devices," Revision 6	ML16019A184
BTP 7–12, "Guidance on Establishing and Maintaining Instrument Setpoints," Revision 6	ML16019A200
BTP 7–13, "Guidance on Cross-Calibration of Protection System Resistance Temperature Detectors," Revision 6	ML16019A240
BTP 7–14, "Guidance on Software Reviews for Digital Computer-Based Instrumentation and Control Systems," Revision 6	ML16019A308
BTP 7–17, "Guidance on Self-Test and Surveillance Test Provisions," Revision 6	ML16019A316
BTP 7–18, "Guidance on the Use of Programmable Logic Controllers in Digital Computer-Based Instrumentation and Control Systems," Revision 6	ML16019A327
BTP 7–19, "Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems," Revision 7	ML16019A344
BTP 7–21, "Guidance on Digital Computer Real-Time Performance," Revision 6	ML16020A036

*No changes resulting from public comments. See documents in the package at ADAMS Accession No. ML16008B013 to see changes made since the last proposed revision.

Dated at Rockville, Maryland, this 25th day of August, 2016.

For the Nuclear Regulatory Commission.

Joseph Colaccino,

Chief, New Reactor Rulemaking and Guidance Branch, Division of Engineering Infrastructure and Advanced Reactors, Office of New Reactors.

[FR Doc. 2016–20873 Filed 8–30–16; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Peace Corps will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

DATES: Submit comments on or before October 31, 2016.

ADDRESSES: Written comments should be addressed to Denora Miller, FOIA/Privacy Act Officer, Office of Management, Peace Corps, 1111 20th Street NW., Washington, DC 20526. Denora Miller may also be contacted by telephone at 202–692–1236 or email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Denora Miller at Peace Corps address above.

SUPPLEMENTARY INFORMATION: The Peace Corps, under Section 10(a)(4) of the Peace Corps Act, authorizes the Director to accept gifts of voluntary service, money, or property, for use in furtherance of the purposes of the Peace Corps Act. The information collected on the donation form is essential to fulfilling this authority and acceptance of gifts.

OMB Control Number: 0420–XXXX.

Title: Donation Form.

Type of Review: New.

Affected public: Individuals or households.

Respondents' obligation to reply: Voluntary.

Burden to the public:

- *Estimated number of respondents:* 13,000.
- *Frequency of response:* One time.
- *Estimated average burden per response:* 10 minutes.

(d) *Estimated total reporting burden:* 2,167 hours.

General Description of Collection: The information pulled from the donation form is used internally and on a daily basis by the Peace Corps Office of Strategic Partnerships (OSP) to coordinate and oversee the development and implementation of partnerships to support the agency's three goals and enhance programs through every stage of the Volunteer life cycle, communication with prospective and current donors.

Request for Comment: Peace Corps invites comments on whether the proposed collection of information is necessary for proper performance of the functions of the Peace Corps Response, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice issued in Washington, DC, on August 25, 2016.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2016–20904 Filed 8–30–16; 8:45 am]

BILLING CODE 6051–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78678; File Nos. SR–NYSE–2011–55; SR–NYSEAmex–2011–84]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE MKT LLC; Order Granting an Extension to Limited Exemptions From Rule 612(c) of Regulation NMS in Connection With the Exchanges' Retail Liquidity Programs Until December 31, 2016

August 25, 2016.

On July 3, 2012, the Securities and Exchange Commission ("Commission") issued an order pursuant to its authority under Rule 612(c) of Regulation NMS ("Sub-Penny Rule") [1] that granted the New York Stock Exchange LLC ("NYSE") and NYSE MKT LLC [2] ("NYSE MKT" and, together with NYSE, the "Exchanges") limited exemptions from the Sub-Penny Rule in connection with the operation of the Exchanges' respective Retail Liquidity Programs ("Programs").[3] The limited exemptions were granted concurrently with the Commission's approval of the Exchanges' proposals to adopt their respective Programs for one-year pilot terms.[4] The exemptions were granted coterminous with the effectiveness of the pilot Programs; both the pilot Programs and exemptions are scheduled to expire on August 31, 2016.[5]

The Exchanges now seek to extend the exemptions until December 31, 2016.[6] The Exchanges' request was made in conjunction with immediately effective filings that extend the operation of the Programs through the same date.[7] In their request to extend the exemptions, the Exchanges note that the participation in the Programs has increased more recently. Accordingly, the Exchanges have asked for additional time to allow themselves and the Commission to analyze more robust data concerning the Programs, which the Exchanges committed to provide to the

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[1] 17 CFR 242.612(c).

[2] At the time it filed the original proposal to adopt the Retail Liquidity Program, NYSE MKT went by the name NYSE Amex LLC. On May 14, 2012, the Exchange filed a proposed rule change, immediately effective upon filing, to change its name from NYSE Amex LLC to NYSE MKT LLC. *See* Securities Exchange Act Release No. 67037 (May 21, 2012), 77 FR 31415 (May 25, 2012) (SR–NYSEAmex–2012–32).

[3] *See* Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR–NYSE–2011–55; SR–NYSEAmex–2011–84) ("Order").

[4] *See id.*

[5] The pilot terms of the Programs were originally scheduled to end on July 31, 2013, but the Exchanges initially extended the terms for an additional year, through July 31, 2014, *see* Securities Exchange Act Release Nos. 70096 (August 2, 2013), 78 FR 48520 (August 8, 2013) (SR–NYSE–2013–48), and 70100 (August 2, 2013), 78 FR 48535 (August 8, 2013) (SR–NYSEMKT–2013–60), and then subsequently extended the terms again through March 31, 2015, *see* Securities Exchange Act Release Nos. 72629 (July 16, 2014), 79 FR 42564 (July 22, 2014) (SR–NYSE–2014–35), and 72625 (July 16, 2014), 79 FR 42566 (July 22, 2014) (SR–NYSEMKT–2014–60), September 30, 2015, *see* Securities Exchange Act Release Nos. 74454 (March 6, 2015), 80 FR 13054 (March 12, 2015) (SR–NYSE–2015–10), and 74455 (March 6, 2015), 80 FR 13047 (March 12, 2015) (SR–NYSEMKT–2015–14), March 31, 2016, *see* Securities Exchange Act Release Nos. 75993 (September 28, 2015), 80 FR 59844 (October 2, 2015) (SR–NYSE–2015–41), and 75995 (September 28, 2015), 80 FR 59836 (October 2, 2015) (SR–NYSEMKT–2015–69), and August 31, 2016, *see* Securities Exchange Act Release Nos. 77426 (March 23, 2016), 81 FR 17533 (March 29, 2016) (SR–NYSE–2016–25), and 77424 (March 23, 2016), 81 FR 17522 (March 29, 2016) (SR–NYSEMKT–2016–39). Each time the pilot terms of the Programs were extended, the Commission granted the Exchanges' requests to also extend the Sub-Penny exemptions through July 31, 2014, *see* Securities Exchange Act Release No. 70085 (July 31, 2013), 78 FR 47807 (August 6, 2013), March 31, 2015, *see* Securities Exchange Act Release No. 72732 (July 31, 2014), 79 FR 45851 (August 6, 2014), September 30, 2015, *see* Securities Exchange Act Release No. 74507 (March 13, 2015), 80 FR 14421 (March 19, 2015), March 31, 2016, *see* Securities Exchange Act Release No. 76020 (September 29, 2015), 80 FR 60201 (October 5, 2015), and August 31, 2016, *see* Securities Exchange Act Release No. 77438 (March 24, 2016), 81 FR 17752 (March 30, 2016).

[6] *See* Letter from Martha Redding, Assistant Secretary, NYSE, to Brent J. Fields, Secretary, Securities and Exchange Commission, dated August 8, 2016.

[7] *See* Securities Exchange Act Release Nos. 78600 (August 17, 2016), 81 FR 57642 (August 23, 2016) (SR–NYSE–2016–54), and 78602 (August 17, 2016), 81 FR 57639 (August 23, 2016) (SR–NYSEMKT–2016–76).

Commission.[8] For this reason and the reasons stated in the Order originally granting the limited exemptions, the Commission finds that extending the exemptions, pursuant to its authority under Rule 612(c) of Regulation NMS, is appropriate in the public interest and consistent with the protection of investors.

THEREFORE, IT IS HEREBY ORDERED that, pursuant to Rule 612(c) of Regulation NMS, each Exchange is granted a limited exemption from Rule 612 of Regulation NMS that allows it to accept and rank orders priced equal to or greater than $1.00 per share in increments of $0.001, in connection with the operation of its Retail Liquidity Program, until December 31, 2016.

The limited and temporary exemptions extended by this Order are subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Securities Exchange Act of 1934. Responsibility for compliance with any applicable provisions of the Federal securities laws must rest with the persons relying on the exemptions that are the subject of this Order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20891 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78698; File No. SR–CBOE–2016–061]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 12, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fees Schedule. Specifically, the Exchange proposes to delete the reference to "Test Center" fees from the Continuing Education Fees sub-section of the Regulatory Fees section of the Fees Schedule to reflect the fact that the Exchange no longer offers test center delivery of the Regulatory Element of the Exchange's continuing education requirement; as of July 5, 2016, delivery of the Regulatory Element of the Exchange's continuing education requirement is entirely Web-based.

On August 8, 2015, the Securities and Exchange Commission ("SEC" or "Commission") approved SR–FINRA–2015–015 and the proposed changes to FINRA Rule 1250 therein, which, among other things, provided for Web-based delivery of the Regulatory Element of certain of FINRA's continuing education programs.[3] Pursuant to SR–FINRA–2015–015, effective October 1, 2015, Web-based delivery has been available for the Regulatory Element for the S106 Continuing Education Program for Investment Company and Variable Contracts Representatives, the S201 Continuing Education Program for Registered Principals and Supervisors, and the S901 Continuing Education Program for Operations Professionals.[4] Web-based delivery of the S101 General Program, the continuing education program for all other registration categories, became available on January 4, 2016, as contemplated by SR–FINRA–2015–015. In addition, pursuant to SR–FINRA–2015–015, test center delivery of the Regulatory Element of the S101, S106, S201, and S901 continuing education programs was to end after January 4, 2016, but in no case more than six months after January 4, 2016 or July 5, 2016.[5] Since July 5, 2016 has passed, going forward, the Regulatory Element of the above-listed continuing education programs is no longer administered at test centers and is only offered via Web-based delivery.

The Exchange utilizes FINRA's continuing education programs for its own continuing education requirements. Consistent with SR–FINRA–2015–015, the Exchange recently filed SR–CBOE–2015–084[6] relating to continuing education. In the filing, the Exchange proposed substantially similar changes to its rules as those set forth in SR–FINRA–2015–015 with respect to Web-based delivery of the Regulatory Element of the S101 General Program, S106 Continuing Education Program for Investment Company and Variable Contracts Representatives, the S201 Continuing Education Program for Registered Principals and Supervisors, and the S901 Continuing Education Program for Operations Professionals. Consistent with SR–CBOE–2015–084, the Exchange also filed SR–CBOE–2015–093 to amend the Fees Schedule to provide that the fee for Web-based delivery of the Regulatory Elements of the S101, S106, S201, and S901 Continuing Education Programs would be $55 as opposed to test center delivery, which would continue to be $100 per session until test center delivery of the Regulatory Element was phased out and the programs were no longer offered at testing centers.[7] In its filing, the Exchange stated that upon cessation of the availability of test-center delivery of the Regulatory Element, the Exchange would submit another fee filing to remove references to test center fees from the Fees Schedule.[8] Accordingly, the Exchange now proposes to amend the Fees Schedule to remove the now-obsolete $100 fee for test center delivery of the Regulatory Element of the Exchange's continuing education requirement.

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[8] *See* Order, *supra* note 3, 77 FR at 40681.

[9] 17 CFR 200.30–3(a)(83).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (Order Approving a Proposed Rule Change to Provide a Web-based Delivery Method for Completing the Regulatory Element of the Continuing Education Requirements) (SR–FINRA–2015–015).

[4] *Id.*

[5] Test-center delivery of the Regulatory Element will be phased out by no later than six months after January 4, 2016. *See* Securities Exchange Act Release No. 75581 (July 31, 2015), 80 FR 47018 (August 6, 2015) (Order Approving a Proposed Rule Change To Provide a Web-Based Delivery Method for Completing the Regulatory Element of the Continuing Education) (SR–FINRA–2015–015).

[6] *Available at http://www.cboe.com/publish/RuleFilingsSEC/SR-CBOE-2015-084.pdf.*

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is consistent with the Act. Primarily, the Exchange believes that the elimination of obsolete rules helps to eliminate confusion and makes the Exchange's rules more clear and transparent, which is in the interests of both market participants and the general public. The Exchange is continuously updating the Rules to provide additional accuracy, detail, clarity, and transparency regarding its operations, trading systems, and fees. The Exchange believes that the adoption of detailed, clear, and transparent rules reduces burdens on competition and promotes just and equitable principles of trade. Furthermore, in general, the Exchange believes that promoting the Web-based delivery method for continuing education serves the best interests of market participant's and the general public by lower the costs of participation in the markets. The reduced cost of Web-based delivery of the Regulatory Element of the S106, S201, and S901 Continuing Education Programs lowers barriers to entry and removes impediments to a free and open market and national market system by making it easier and less costly for Trading Permit Holders to participate in the market. The Exchange believes that reducing the costs of continuing education promotes regulatory compliance, which is in the best interests of investors, consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed rule change merely seeks to delete references to a fee that is no longer applicable to any Trading Permit Holder under the Rules. In fact, the Exchange believes that the proposed rule change will relieve any burden on, or otherwise promote, competition by lower costs of entry to the markets and making it easier for market participants to satisfy the Regulatory Element of the Exchange's continuing education requirement.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and paragraph (f) of Rule 19b–4 [13] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–CBOE–2016–061 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE-*2016–061*. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–

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[7] *See* Securities Exchange Act Release No. 76352 (November 4, 2015), 80 FR 69760 (November 10, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule) (SR–CBOE–2015–093).

[8] *See id.*

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f).

016–061 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20965 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78684; File No. SR–CHX–2016–15]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the Handling of Intermarket Sweep Orders

August 25, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on August 17, 2016, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend the Rules of the Exchange (''CHX Rules'') to modify the handling of Intermarket Sweep Orders (''ISOs'').

CHX has designated this proposed rule change as non-controversial pursuant to Section 19(b)(3)(A) [3] of the Act and Rule 19b–4(f)(6) [4] thereunder and has provided the Commission with the notice required by Rule 19b–4(f)(6)(iii).[5]

The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

1. Purpose

The Exchange proposes various amendments to the CHX Rules to amend the operation of the Exchange's ISO modifiers as follows:

- Amend the operation of the ISO modifier to be similar to the ISO modifiers offered by other national securities exchanges.[6] As amended, a limit order marked ISO (''ISO limit'') would behave like a simple limit order [7] (*i.e.*, executable through multiple price points not beyond its limit price with the unexecuted balance to be immediately cancelled or ranked on the CHX book depending on the attached Time-In-Force [8] and display modifier [9]), but without regard to the Protected Quotations [10] of away markets when it is being processed as a new incoming order.
- Require a limit order marked by any one of the Exchange's three ISO modifiers (*i.e.*, BBO ISO,[11] Price-Penetrating ISO,[12] and ISO [13]) to be handled as if it were marked ISO, as amended.[14]

The Exchange also proposes to clarify the current handling of cross orders [15] marked ISO (''ISO cross'') and Participants' [16] obligations with respect to ISOs.

The Exchange believes that the proposed rule change will harmonize the operation of the Exchange's ISO modifier with ISO modifiers offered by other national securities exchanges, as well as clarify and simplify the order types and modifiers offered by the Exchange, all of which further the objectives of the Act, as described below.

Current CHX ISOs

The Exchange currently offers three different ISO modifiers: BBO ISO, Price-Penetrating ISO, and ISO.[17] While all three modifiers can be used to mark an order as required by Rule 600(b)(30) of Regulation NMS,[18] each modifier is handled differently by the CHX Matching System (''Matching System'').[19]

An incoming BBO ISO will execute against orders resting on the CHX book at prices not to exceed the more restrictive of its limit price or the contra-side displayed best bid or offer. Any unexecuted balance of the BBO ISO will be immediately cancelled if -1- marked Immediate Or Cancel (''IOC'') [20] or -2- the incoming BBO ISO sell (buy) order could execute against any resting order(s) priced below (above) the displayed best bid (offer), regardless of the Time-In-Force. If the unexecuted balance of the BBO ISO would not be cancelled as described above, it will be ranked on the CHX Book and will be displayable at its limit price. A limit order marked BBO ISO may not be marked Do Not Display.[21] The Matching System, in executing the ISO as soon as the order is received by the Matching System, will not take any of the actions described in Article 20, Rule 5 to prevent an improper trade-through or any of the actions described in Article 20, Rule 6 to prevent a locked or crossed market; provided, however, that in executing any initially unexecuted balance of the ISO that is placed in the Matching System, the requirements of Article 20, Rule 5 will be followed. These orders shall be executed on the assumption that the Participant routing the order to the Matching System has already satisfied the quotations of other markets as required by Rule 600(b)(30) [22] and shall be displayed because the Participant routing the order to the Matching System has already satisfied the quotations of other markets as required by Article 20, Rule 6(c)(3). A limit order marked BBO ISO shall be deemed to have been received Do Not Route,[23] which cannot be overridden by the order sender.

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[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 240.19b–4(f)(6)(iii).

[6] *See e.g.*, NYSE ARCA Equities Rule 7.31(e)(2); *see also e.g.*, Bats BYX Rule 11.9(d).

[7] *See* CHX Article 1, Rule 2(a)(1).

[8] *See* CHX Article 1, Rule 2(d).

[9] *See* CHX Article 1, Rule 2(e).

[10] *See* 17 CFR 242.600(b)(58).

[11] *See* CHX Article 1, Rule 2(b)(1)(A).

[12] *See* CHX Article 1, Rule 2(b)(1)(E).

[13] *See* CHX Article 1, Rule 2(b)(3)(B).

[14] In order to facilitate the transition to the amended ISO, the Exchange does not propose to eliminate the BBO ISO and Price-Penetrating ISO modifiers at this time.

[15] *See* CHX Article 1, Rule 2(a)(2).

[16] A ''Participant'' is a ''member'' of the Exchange for purposes of the Act. *See* CHX Article 1, Rule 1(s).

[17] BBO ISO and Price-Penetrating ISOs are limit order modifiers, whereas ISO is a limit and cross order modifier. The Exchange last modified the operation of BBO ISO and Price-Penetrating ISO in 2014. *See* Securities Exchange Act Release No. 73572 (November 10, 2014), 79 FR 68736 (November 18, 2014) (SR–CHX–2014–18).

[18] *See* 17 CFR 242.600(b)(30).

[19] The Matching System is an automated order execution system, which is a part of the Exchange's ''Trading Facilities,'' as defined under CHX Article 1, Rule 1(z).

[20] *See* CHX Article 1, Rule 2(d)(4).

[21] *See* CHX Article 1, Rule 2(c)(2).

[22] 17 CFR 242.600(b)(30).

A Price-Penetrating ISO will execute at or better than its limit price as soon as the order is received by the Matching System, with any unexecuted balance of the order to be immediately cancelled, as it is always handled IOC. A Price-Penetrating ISO cannot be displayed or otherwise post to the CHX book. Price-Penetrating ISOs will execute against any eligible orders in the Matching System (including any Reserve Size or undisplayed orders) through multiple price points. The Matching System, in executing these orders, will not take any of the actions described in Article 20, Rule 5 to prevent an improper trade-through. A limit order marked Price-Penetrating ISO shall be deemed to have been received IOC, which cannot be overridden by the order sender.

ISO is a limit and cross order modifier. A limit order marked ISO that is not marked BBO ISO is deemed to have been received Price-Penetrating ISO, which cannot be overridden by the order sender. Thus, a limit order marked ISO will always be handled as a BBO ISO or Price-Penetrating ISO. A cross order marked ISO is handled like a simple cross order, except that the Exchange would not take any actions described in Article 20, Rule 5 to prevent an improper trade-through.[24]

Amended CHX ISOs

The Exchange now proposes to amend the definition of "ISO" under Article 1, Rule 2(b)(3)(B) so that the amended ISOs behave like ISOs offered by other national securities exchanges.[25] Specifically, the Exchange proposes to amend the definition of ISO to -1- require an ISO limit to behave like a simple limit order (*i.e.,* executable through multiple price points not beyond its limit price with the unexecuted balance to be immediately cancelled or posted to the CHX book depending on the attached Time-In-Force), but without regard to the Protected Quotations of away markets when it is being processed as a new incoming order; [26] -2- provide that the default Time-In-Force for an ISO limit is IOC, unless it is marked with another available Time-In-Force [27] (*i.e.,* Day [28] or GTD); [29] -3- clarify the current applicability of the ISO modifier to cross orders; -4- clarify that it is the Participant's responsibility in complying with the requirements of Regulation NMS when submitting an ISO to the Exchange; and -5- delete obviated language. The mechanical result of these proposed amendments is that an amended ISO limit will behave like the current Price-Penetrating ISO, except that the amended ISO limit may have a Time-In-Force other than IOC, which would permit the unexecuted balance of the amended ISO limit to be ranked on the CHX book and displayable at its limit price. To this end, amended Article 1, Rule 2(b)(3)(B) provides as follows:

> "Intermarket Sweep" or "ISO": a limit or cross order modifier that marks an order as required by SEC Rule 600(b)(30).[30] The Exchange relies on the marking of an order as an ISO when handling such an order, and thus, it is the entering Participant's responsibility, not the Exchange's responsibility, to comply with the requirements of Regulation NMS and Article 20, Rule 6(c)(3) [31] relating to ISOs. Any new incoming order marked ISO will not be rejected or cancelled if it would lock, cross, or trade-through a Protected Quotation of an away market. ISOs shall be deemed to have been received "Do Not Route," as defined under paragraph (b)(3)(A), which cannot be overridden by the order sender.
>
> (i) *ISO limit.* A new incoming limit order marked ISO ("ISO limit") may be executed at one or multiple price levels in the Matching System without regard to Protected Quotations at away markets consistent with Regulation NMS. All ISO limits shall be deemed to have been received IOC, unless an ISO limit is marked with another Time-In-Force.
>
> (ii) *ISO cross.* A cross order marked ISO ("ISO cross") may execute at its crossing price as soon as it is received by the Matching System without regard to Protected Quotations at away markets consistent with Regulation NMS. An ISO cross that could not be immediately executed within the Matching System upon receipt shall be immediately cancelled.[32]

The Exchange also proposes to amend Article 1, Rule 2(b)(1)(A) and Article 1, Rule 2(b)(1)(E) to delete the current definition of BBO ISO and Price-Penetrating ISO, respectively, and replace each definition with language that provides that the modifier is a limit order modifier that shall be handled as an ISO, as defined under amended paragraph (b)(3)(B).[33] Moreover, so as to contemplate the proposed default IOC handling of ISO limits, the Exchange proposes to amend the definition of "Limit order" under Article 1, Rule 2(a)(1) to provide that all limit orders, except those marked Price-Penetrating ISO, BBO ISO, and ISO, shall be deemed to have been received Day, if an order duration modifier is not specified.

Interaction With Certain Order Modifiers

The Exchange notes that the amended ISO would be compatible with all display modifiers (*i.e.,* Always Quote,[34] Do Not Display,[35] and Reserve Size [36]). A new incoming ISO limit marked Day and Do Not Display would be permitted to trade-through and/or lock or cross Protected Quotations of away markets and the unexecuted balance would be ranked on the CHX book at its limit price. Similarly, a new incoming ISO limit marked Day and Reserve Size would be permitted to trade-through and/or lock or cross Protected Quotations of away markets and the unexecuted balance would be ranked on the CHX book at its limit price with the displayable portion displayed at its limit price. Also, an ISO limit marked Day and Always Quote would be permitted to trade-through and/or lock or cross Protected Quotations of away markets and the unexecuted balance would be ranked on the CHX book if it could be displayed at its limit price or cancelled if it could not be displayed at its limit price.

Moreover, if the Exchange were to receive an ISO limit marked CHX

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[23] *See* CHX Article 1, Rule 2(b)(3)(A).

[24] In eliminating the definition of "ISO Cross" in 2013, the Exchange explained that "ISO Cross is simply a cross order marked ISO and not a distinct order modifier." *See* Exchange Act Release No. 69538 (May 8, 2013), 78 FR 28671 (May 15, 2013) (SR–CHX–2013–10).

[25] *See supra* note 6.

[26] The Exchanges notes that the current BBO ISO may be ranked on the CHX book if it is -1- not marked IOC and -2- does not execute against any contra-side orders within the Matching System at prices inferior to the then-current best displayed contra-side order on the CHX book. *See* current CHX Article 1, Rule 2(b)(1)(A). As proposed, an ISO will be permitted to be ranked on the CHX book even if a portion of the ISO executes against contra-side orders within the Matching System at prices inferior to the then-current best displayed contra-side order on the CHX book.

[27] The Exchange notes that the Fill Or Kill modifier, as defined under CHX Article 1, Rule 2(d)(2), has been unavailable since December 4, 2013. Any order marked FOK will be rejected upon receipt. *See* CHX Market Regulation Department Information Memorandum No. MR–13–12 (December 3, 2013).

[28] *See* CHX Article 1, Rule 2(d)(1).

[29] *See* CHX Article 1, Rule 2(d)(3).

[30] See 17 CFR 242.600(b)(30).

[31] CHX Article 20, Rule 6(c)(3) excepts a Participants [sic] from the locked and crossed markets prohibition described under CHX Article 20, Rule 6(b) if "The Exchange Participant displaying the locking or crossing quotation simultaneously routed an intermarket sweep order to execute against the full displayed size of any locked or crossed protected quotation."

[32] Cross orders are always handled IOC. *See* CHX Article 1, Rule 2(a)(2).

[33] *See supra* note 14.

[34] *See* CHX Article 1, Rule 2(c)(1).

[35] *See* CHX Article 1, Rule 2(c)(2).

[36] *See* CHX Article 1, Rule 2(c)(3).

Only,[37] the Exchange will ignore the CHX Only modifier and handle the ISO limit as if it were not marked CHX Only, which is consistent with current practice.[38] This is because the ISO and CHX Only modifiers are incompatible in that ISO instructs the Exchange to ignore the Protected Quotations of away markets when initially processing the order, whereas CHX Only requires the Exchange to price slide the order upon initial receipt to prevent locked and crossed markets.

Examples

The following Examples are illustrative of the amended ISO modifier, but do not exhaustively depict every possible scenario regarding ISOs. Moreover, the Examples do not necessarily depict the actual technical processes of prioritizing messages and executing orders.

Example 1. Assume that proposed rule change is operative and the following:

- The NBBO for security XYZ is 10.00 x 10.01.
- The displayed CHX BBO for XYZ is 9.99 x 10.01.
- There is only one buy order for XYZ priced at 9.99 resting on the CHX book ("CHX Buy Order") and there are no undisplayed orders for XYZ resting on the CHX book.
- There is only one away market with a Protected Bid for XYZ at 10.00 ("Away Protected Bid").
- All Protected Quotations in XYZ are for 100 shares.

Assume then that the Exchange receives an ISO limit marked Day to sell 200 shares of XYZ at 9.99 ("Incoming Sell ISO Limit").

Under this Example 1, the Exchange would execute 100 shares of Incoming Sell ISO Limit against the CHX Buy Order at 9.99, without taking any actions to prevent a trade-through of Away Protected Bid. The Exchange would then rank and display the unexecuted 100 shares of Incoming Sell ISO Limit at 9.99, without taking any actions to prevent a crossed market.

Example 2. Assume the same as Example 1, except that Incoming Sell ISO Limit is not marked with a Time-In-Force. Under Example 2, the unexecuted balance of Incoming Sell ISO Limit would be cancelled, as the default handling for ISO limits is IOC.

Example 3. Assume the same as Example 1, except that Incoming Sell ISO Limit is marked Price-Penetrating ISO or BBO ISO and is also marked Day. Under Example 3, Incoming Sell ISO Limit would be handled as if it were marked ISO and would behave identically as described under Example 1.

Example 4. Assume the same as Example 1, except that Incoming Sell ISO Limit is marked Price-Penetrating ISO or BBO ISO and is not marked by a Time-In-Force. Under this Example 4, the Exchange would cancel the unexecuted balance of Incoming Sell ISO Limit, as an ISO that does not have a Time-In-Force identified would be handled IOC.

Operative Date

The proposed rule change shall be operative pursuant to notice to Participants on a date after the expiration of the 30-day preoperative waiting period.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general,[39] and furthers the objectives of Section 6(b)(5) in particular,[40] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments and perfect the mechanisms of a free and open market, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Specifically, the Exchange submits that harmonizing the operation of the ISO modifier with the ISO modifiers offered by other national securities exchanges, such as NYSE Arca and Bats BYX, would provide market participants with consistent and predictable handling of ISOs, which would facilitate their compliance with Regulation NMS regarding the use of ISOs, thereby removing impediments and perfecting the mechanisms of a free and open market.

Moreover, the Exchange believes that requiring the Exchange's various ISO modifiers to operate in the same manner and clarifying the handling of ISO crosses simplifies the CHX Rules, which furthers the objectives of Section 6(b)(1)[41] in that it further enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its Participants and persons associated with its Participants, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange.

B. Self-Regulatory Organization's Statement of Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed rule change will reduce the regulatory burden placed on market participants engaged in trading activities across different markets by harmonizing the operation of the Exchange's ISO modifier with those of other national securities exchanges. The Exchange believes that such harmonization across the various markets will reduce burdens on competition by removing impediments to participation in the national market system.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Changes Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Changes and Timing for Commission Action

The Exchange believes that the proposal qualifies for immediate effectiveness upon filing as non-controversial under Section 19(b)(3)(A) of the Act[42] and paragraph (f)(6) of Rule 19b–4 thereunder.[43]

The Exchange asserts that the proposed rule change: (1) Will not significantly affect the protection of investors or the public interest, (2) will not impose any significant burden on competition, and (3) and will not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate. In addition, the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing, or such shorter time as designated by the Commission.[44] The Exchange believes that the proposed rule change raises no novel issues, as the amended ISO modifier will operate similarly to the ISO modifiers of other national securities exchanges, such as NYSE Arca and Bats BYX.[45] As such, the Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) of the Act[46] and paragraph (f)(6) of Rule 19b–4 thereunder.[47]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) of the Act[48] to determine whether the proposed rule should be approved or disapproved.

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[37] *See* CHX Article 1, Rule 2(b)(1)(C).

[38] *See* Securities Exchange Act Release No. 69075 (March 8, 2013), 78 FR 16311 (March 14, 2013) (SR–CHX–2013–07).

[39] 15 U.S.C. 78f(b).

[40] 15 U.S.C. 78f(b)(5).

[41] 15 U.S.C. 78f(b)(1).

[42] 15 U.S.C. 78s(b)(3)(A).

[43] 17 CFR 240.19b–4.

[44] 17 CFR 240.19b–4(f)(6)(iii).

[45] *See supra* note 6.

[46] 15 U.S.C. 78s(b)(3)(A).

[47] 17 CFR 240.19b–4.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CHX–2016–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–CHX–2016–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File No. SR–CHX–2016–15 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[49]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20885 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

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[48] 15 U.S.C. 78s(b)(2)(B).

[49] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78677; File No. SR–NYSEArca–2013–107]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Liquidity Program Until December 31, 2016

August 25, 2016.

On December 23, 2013, the Securities and Exchange Commission ("Commission") issued an order pursuant to its authority under Rule 612(c) of Regulation NMS ("Sub-Penny Rule")[1] that granted NYSE Arca, Inc. ("Exchange") a limited exemption from the Sub-Penny Rule in connection with the operation of the Exchange's Retail Liquidity Program ("Program").[2] The limited exemption was granted concurrently with the Commission's approval of the Exchange's proposal to adopt the Program for a one-year pilot term.[3] The exemption was granted coterminous with the effectiveness of the pilot Program; both the pilot Program and exemption are scheduled to expire on August 31, 2016.[4]

The Exchange now seeks to extend the exemption until December 31, 2016.[5] The Exchange's request was made in conjunction with an immediately effective filing that extends the operation of the Program through the same date.[6] In its request to extend the exemption, the Exchange notes that the participation in the Program has increased more recently. Accordingly, the Exchange has asked for additional time to allow itself and the Commission to analyze more robust data concerning the Program, which the Exchange committed to provide to the Commission.[7] For this reason and the reasons stated in the Order originally granting the limited exemption, the Commission finds that extending the exemption, pursuant to its authority under Rule 612(c) of Regulation NMS, is appropriate in the public interest and consistent with the protection of investors.

THEREFORE, IT IS HEREBY ORDERED that, pursuant to Rule 612(c) of Regulation NMS, the Exchange is granted a limited exemption from Rule 612 of Regulation NMS that allows it to accept and rank orders priced equal to or greater than $1.00 per share in increments of $0.001, in connection with the operation of its Retail Liquidity Program, until August 31, 2016.

The limited and temporary exemption extended by this Order is subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Securities Exchange Act of 1934. Responsibility for compliance with any applicable provisions of the Federal securities laws must rest with the persons relying on the exemption that is the subject of this Order.

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[1] 17 CFR 242.612(c).

[2] *See* Securities Exchange Act Release No. 71176 (December 23, 2013), 78 FR 79524 (December 30, 2013) (SR–NYSEArca–2013–107) ("Order").

[3] *See id.*

[4] The pilot term of the Program was originally scheduled to end on April 14, 2015, but the Exchange initially extended the term through September 30, 2015, *see* Securities Exchange Act Release No. 74572 (March 24, 2015), 80 FR 16705 (March 30, 2015) (NYSEArca–2015–22), and then subsequently extended the term again through August 31, 2016, *see* Securities Exchange Act Release Nos. 75994 (September 28, 2015), 80 FR 59834 (October 2, 2015) (SR–NYSEArca–2015–84), 77236 (Feb. 25, 2016), 81 FR 10943 (March 2, 2016) (SR–NYSEArca–2016–30), and 77425 (March 23, 2016), 81 FR 17523 (March 29, 2016) (SR–NYSEArca–2016–47). Each time the pilot term of the Program was extended, the Commission granted the Exchange's request to also extend the Sub-Penny exemption through September 30, 2015, *see* Securities Exchange Act Release No. 74609 (March 30, 2015), 80 FR 18272 (April 3, 2015), March 31, 2016, *see* Securities Exchange Act Release No. 34–76021 (September 29, 2015), 80 FR 60207 (October 5, 2015), and August 31, 2016, *see* Securities Exchange Act Release No. 34–77437 (March 24, 2016), 81 FR 17752 (March 30, 2016).

[5] *See* Letter from Martha Redding, Assistant Secretary, NYSE, to Brent J. Fields, Secretary, Securities and Exchange Commission, dated August 8, 2016.

[6] *See* Securities Exchange Act Release No. 78601 (August 17, 2016), 81 FR 57632 (August 23, 2016) (SR–NYSEArca–2016–113).

[7] *See* Order, *supra* note 2, 78 FR at 79529.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20884 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78673; File No. SR–NYSEMKT–2016–79]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Rules Relating to Pre-Opening Indications and Opening Procedures

August 25, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 16, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules relating to pre-opening indications and opening procedures to promote greater efficiency and transparency at the open of trading on the Exchange. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules relating to pre-opening indications and opening procedures to promote greater efficiency and transparency at the open of trading on the Exchange. In particular, the Exchange proposes to:

- Make changes to the rules related to the pre-opening indication process by:
  - ○ Amending Rules 15—Equities ("Rule 15") and 123D—Equities ("Rule 123D") to consolidate the requirements for publication of pre-open indications in a single rule (Rule 15);
  - ○ changing the conditions in which a Designated Market Maker ("DMM") is required to publish a pre-opening indication in a security to an anticipated 5% move from a security's reference price and, during extreme market-wide volatility, an anticipated 10% from a security's reference price; and
  - ○ providing for the CEO of the Exchange to temporarily suspend the requirement to publish pre-opening indications.
- Make changes to Rule 123D related to the opening process by:
  - ○ Incorporating all procedures relating to openings, other than pre-opening indications, in Rule 123D; and
  - ○ Specifying that DMMs may effect an opening of a security electronically within specified percentage and volume parameters, which would be doubled during extreme market-wide volatility; and
  - ○ providing for the CEO of the Exchange to temporarily suspend price and volume limitations for a DMM automated open or the requirement for prior Floor Approval before opening or reopening a security.
- Delete Rule 48—Equities ("Rule 48").
- Make conforming changes to Rules 80C—Equities ("Rule 80C") and 9217.

The Exchange believes that the proposed changes will enhance transparency regarding the Exchange's opening process by specifying new parameters for how the opening at the Exchange would be effectuated on trading days experiencing extreme market-wide volatility, which would include both additional information before the open through the use of new parameters for pre-opening indications and expanded ability for DMMs to effectuate an opening electronically. The proposed rule changes are designed to preserve the Exchange's existing model, which values human touch when opening securities with significant price or volume disparity, while at the same time promoting automated measures to have as many securities open as close to 9:30 a.m. as feasible, even during extreme market-wide volatility.

These proposed changes are based on recent amendments to the rules of the New York Stock Exchange LLC ("NYSE").[4]

Background

The Exchange's current pre-opening procedures are outlined in Rules 15 (Pre-Opening Indications), 48 (Exemptive Relief—Extreme Market Volatility Condition), and 123D (Openings and Halts in Trading).

Rule 15(a) provides that if the opening transaction in a security will be at a price that represents a change of more than the "applicable price change" specified in the Rule,[5] the DMM arranging the opening transaction or the Exchange shall issue a pre-opening indication ("Rule 15 Indication"), which represents a price range in which a security is anticipated to open.

A Rule 15 Indication is published on the Exchange's proprietary data feeds only and includes the security and the price range within which the DMM anticipates the opening transaction will occur, and would include any orally-represented Floor broker interest for the open. The applicable price ranges for determining whether to publish a Rule 15 Indication are based on five different price buckets and are expressed in dollar and percentage parameters:

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[8] 17 CFR 200.30–3(a)(83).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 78228 (July 5, 2016), 81 FR 44907 (July 11, 2016) (SR–NYSE–2016–24) ("NYSE Approval Order"); and Securities Exchange Act Release No. 78512 (August 9, 2016) (SR–NYSE–2016–53) (Notice of Filing).

[5] In current Rule 15, other than for certain American Depositary Receipts ("ADRs"), the "applicable price change" is measured from a security's last reported sale price on the Exchange, the security's offering price in the case of an initial public offering ("IPO"), or the security's last reported sale price on the market from which it is being transferred. For an ADR where the trading day of the underlying security in the primary foreign market for the ADR concludes after the previous day's trading in the U.S. has ended, the "applicable price change" is measured from closing price of the primary foreign market. For an ADR where the primary foreign market on which the underlying security is open for trading at the time of the opening of the Exchange, the "applicable price change" is measured from parity with the last sale price of the underlying security.

Exchange closing price	Applicable price change (more than)
Under $20.00	$0.50
$20–$49.99	$1.00
$50.00–$99.99	$2.00
$100–$500	$5.00
Above $500	1.5%

Rule 123D also mandates that pre-opening indications be published if the opening price would result in a significant price change from the previous close or if the opening is delayed past 10:00 a.m. Eastern Time ("Rule 123D Mandatory Indication"). The DMM is responsible for publishing the Rule 123D Mandatory Indication and, when determining the price range for the indication, takes into consideration Floor broker interest that has been orally entered and what, at a given time, the DMM anticipates the dealer participation in the opening transaction would be. Rule 123D Mandatory Indications are published to the Consolidated Tape and proprietary data feeds. The applicable price ranges for determining whether an opening price would be a "significant" price change requiring a Rule 123D Mandatory Indication are based on three price buckets and are expressed in a mixture of dollar (1 point = one dollar) and percentage parameters:

Previous NYSE closing price	Price change (equal to or greater than)
Under $10.00	1 point.
$10–$99.99	the lesser of 10% or 3 points.
$100 and Over	5 points.

Rule 48 provides that a "qualified Exchange officer"[6] can invoke an extreme market volatility condition at the open (or reopen of trading following a market-wide halt of securities) during which time the Exchange can suspend the requirements of Rules 15 and 123D, and in particular, the requirement to publish pre-opening indications. Rule 48, which was first adopted by NYSE, is intended to be invoked only in those situations where the potential for extreme market volatility would likely impair Floor-wide operations at the Exchange by impeding the fair and orderly opening or reopening securities.[7]

Finally, Rule 123D, which in addition to setting forth requirements for certain pre-opening indications, also specifies procedures relating to openings, including that it is the responsibility of each DMM to ensure that securities open as close to the opening bell as possible and that securities can be opened on a trade or a quote. The rule further provides that openings may be effectuated manually or electronically.

Proposed Rule Change

The Exchange proposes to amend Rules 15, 48, and 123D to introduce greater efficiency and transparency into its opening process by, among other things, consolidating its rules regarding pre-opening indications into a single rule (Rule 15), introducing a new, single percentage parameter for the publication of pre-opening indications that would double on volatile trading days, and consolidating opening procedures into Rule 123D, including specifying parameters of when a DMM may effect an opening electronically, and consolidating the procedures of Rule 48 into Rules 15 and 123D, as applicable. The Exchange also proposes conforming changes to Rules 80C and 9217.

Pre-Opening Indications

The Exchange proposes to make changes to the pre-opening indication process. The Exchange would consolidate the requirements relating to pre-opening indications into Rule 15(a)–(f). Because the Exchange proposes all new rule text in Rule 15(a)–(f), the Exchange proposes to delete paragraphs (a) and (b) of current Rule 15, re-number Rule 15(c) as Rule 15(g), delete rule text in Rule 123D(b) relating to mandatory indications, and amend the title of Rule 15 to add the phrase "and Opening Order Imbalance Information" so that the rule would be titled "Pre-Opening Indications and Opening Order Imbalance Information." In amending Rule 15, the Exchange would establish new conditions for when DMMs are required to publish pre-opening indications.

Proposed Rule 15(a), entitled "Pre-Opening Indications," would provide that a pre-opening indication would include the security and the price range within which the opening price is anticipated to occur. This proposed rule text is based on the last clause of the first sentence of current Rule 15(a), which provides that a pre-opening indication includes the security and the price range within which the opening transaction is anticipated to occur. Proposed Rule 15(a) would further provide that a pre-opening indication would be published via the securities information processor ("SIP") and proprietary data feeds. This proposed rule text is based on the way in which Rule 123D Mandatory Indications are currently published to both the SIP and proprietary data feeds. The Exchange proposes to use the term "securities information processor" instead of "Consolidated Tape" to use the term more commonly used in the industry.[8]

Proposed Rule 15(b), entitled "Conditions for Publishing a Pre-Open Indication," would set forth the conditions in which a DMM is required to publish a pre-opening indication.

- Proposed Rule 15(b)(1) would provide that a DMM will publish a pre-opening indication before a security opens if the opening transaction on the Exchange is anticipated to be at a price that represents a change of more than the "Applicable Price Range," as defined in proposed Rule 15(d), from a specified "Reference Price," as defined in proposed Rule 15(c), before the security opens. The procedures for publishing a pre-opening indication would be described in Rule 15(e). This proposed rule text is based on current Rule 15(a), which uses the term "applicable price range" and describes the reference prices used for purposes of current Rule 15(a). The Exchange proposes to define the "Reference Price" and "Applicable Price Range" in proposed Rules 15(c) and (d), described below. The requirement for DMMs to publish pre-opening indications is based on current Rule 15(a), which provides that the DMM shall issue a pre-opening indication if the conditions set forth in the rule are met.
- Proposed Rule 15(b)(2) would specify that when making a determination of what the opening transaction price would be, the DMM will take into consideration all interest eligible to participate in the opening transaction, including electronically-entered orders, the DMM's own interest, and any interest represented orally in the crowd. This proposed rule text would be new and is designed to promote transparency in Exchange rules that all interest eligible to participate in the opening transaction is considered when publishing a pre-opening indication.
- Proposed Rule 15(b)(3) would provide that if a DMM is unable to publish a pre-opening indication for one or more securities due to a systems or technical issue, the Exchange may publish the pre-opening indication. This proposed rule text is based in part on current Rule 15(a), which provides that

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[6] A "qualified Exchange officer" means the Chief Executive Officer of ICE, or his or her designee, or the Chief Regulatory Officer of the Exchange, or his or her designee.

[7] *See* Securities Exchange Act Release No. 56920 (December 6, 2007), 72 FR 70915 (December 13, 2007) (SR–NYSE–2007–111) ("NYSE Rule 48 Notice of Filing").

[8] *See, e.g.,* Supplementary Material .01 to Rule 19—Equities.

either the DMM or the Exchange shall publish a pre-opening indication. The Exchange proposes a substantive difference to provide that the Exchange "may" rather than "shall" publish a pre-opening indication. As set forth in current Rule 123D(a)(5), which was added after the applicable rule text in Rule 15(a),[9] if a DMM is unavailable to open a security and the Exchange opens trading, the Exchange will not publish a pre-opening indication. Because the Exchange is not obligated to publish pre-opening indications in such scenario, the Exchange proposes to make Rule 15(b)(3) consistent with that rule.

Proposed Rule 15(c), entitled "Reference Price," would provide in paragraph (1) that the Reference Price for a security (other than an American Depository Receipt ("ADR")) for purposes of the proposed rule would be:

- The security's last reported sale price on the Exchange (proposed Rule 15(c)(1)(A));
- in the case of an IPO, the security's offering price (proposed Rule 15(c)(1)(B)); or
- the security's last reported sale price on the securities market from which the security is being transferred to the Exchange, on the security's first day of trading on the Exchange (proposed Rule 15(c)(1)(C)).

This proposed rule text is based on current Rule 15(a).[10]

Proposed Rule 15(c)(2) would provide that the Reference Price for ADRs for purposes of the proposed rule would be:

- The closing price of the security underlying the ADR in the primary foreign market in such security when the trading day of the primary foreign market concludes (proposed Rule 15(c)(2)(A)); or
- based on parity with the last sale price of the security underlying the ADR in the primary foreign market for such security when the trading day of the primary foreign market is open for trading at the time of the opening on the Exchange (proposed Rule 15(c)(2)(B)).

This proposed rule text is based on current Rule 15(b), with non-substantive differences for clarity and to use the defined term "Reference Price" in the proposed rule text.[11] Proposed Rule 15(c)(3) would further provide that the Reference Price for reopening a security following a halt would be the security's last reported sale price on the Exchange. The Exchange proposes to specify the Reference Price for reopening following a halt because the Reference Price would be the same for all securities, including ADRs, which would be trading on the Exchange.

Proposed Rule 15(d) would set forth the Applicable Price Ranges for determining whether a DMM is required to disseminate a pre-opening indication. The Exchange proposes to eliminate the current price buckets in Rules 15 and 123D and instead use a single percentage parameter as the Applicable Price Range for all securities, regardless of price of the security. As proposed, except during extreme market-wide volatility as set forth in proposed Rule 15(d)(2), a DMM would be required to publish a pre-opening indication if a security is expected to open at a price more than 5% away from the Reference Price. The Exchange believes that the proposed 5% parameter applicable to all securities would simplify and streamline the Exchange's rules regarding required pre-opening indications by having a single percentage parameter that would be applied across all securities, rather than having different price buckets and percentage parameter ranges to track. The Exchange further believes that the proposed single percentage parameter would result in a similar number of pre-opening indications as are currently published pursuant to Rule 123D, while at the same time simplifying the process for DMMs.

For example, using trade data on NYSE for the month of October 2015, which was a month of relative trading stability and volumes, current Rule 123D Mandatory Indication parameters required indications for 15 securities on an average daily basis, which represents approximately 0.46% of the securities traded on the Exchange.[12] Applying the proposed new percentage parameter of 5% to the same October 2015 NYSE trade data, NYSE DMMs would have been required, on average, to publish 33 pre-opening indications, which represents 1.01% of securities that trade on NYSE. The Exchange believes that the incremental increase in number of pre-opening indications that would have been published pursuant to the proposed new single percentage parameter would promote transparency in the opening of securities.[13]

Under current rules, the Exchange may suspend the requirement to publish pre-opening indications if a market-wide extreme market volatility condition is declared under Rule 48. This rule was adopted, in part, because of the manual nature of publishing pre-opening indications, and if DMMs were required to publish Rule 123D Mandatory Indications for multiple securities, it could delay the opening process and result in a large number of securities opening past 9:30 a.m. Eastern Time.[14] Historically, the Exchange has declared such a condition if, before the opening of trading, the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures. However, based on the events of the week of August 24, 2015, when the Exchange declared extreme market volatility conditions on August 24, 25, and 26, the Exchange appreciates that the absence of any pre-opening indications may leave a void in the information available for market participants to assess the price at which a security may open. Yet, because market-wide volatility would cause the price of most or all securities to move significantly away from the last sale price on the Exchange, the Exchange believes that the 5% price move appropriate for "normal" trading days would result in a DMM being required to disseminate more pre-opening indications than is feasible.

Accordingly, the Exchange proposes to amend its rules to provide that on trading days with extreme market-wide volatility, the Applicable Price Range would be 10%, or double the Applicable Price Range on regular trading days. Specifically, proposed Rule 15(d)(2) would provide that, if as of 9:00 a.m. Eastern Time ("ET"), the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures, when reopening trading following a market-wide trading halt under Rule 80B, or if the Exchange determines that it is necessary or appropriate for the maintenance of a fair and order market, a DMM would be required to publish a pre-opening indication in a security if the price of that security is expected to open at a price more than 10% away from the Reference Price. By proposing to specify the conditions in which the Applicable Price Range would be 10%, the Exchange would promote transparency in Exchange rules so that market participants will know when the double-wide percentage parameter would be applied. Because the standard for extreme market-wide volatility would be specified in the rule, the Exchange would not need to provide separate notification on a trading day when the double-wide percentages would be applicable.

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[9] *See* Securities Exchange Act Release No. 76292 (Oct. 28, 2015), 80 FR 67830 (Nov. 3, 2015) (SR–NYSEMKT–2015–81).

[10] *See supra* note 5.

[11] The seventh paragraph of Rule 123D(b), which the Exchange proposes to delete, similarly describes the reference price to be used for a foreign-listed security.

[12] Because NYSE MKT currently uses the same equities trading platform as NYSE, and because NYSE has a larger number of securities trading than NYSE MKT, the Exchange believes the NYSE data is representative of how the changes would impact NYSE MKT. Accordingly, all data reference points in this proposed rule change are based on NYSE data.

[13] For purposes of this analysis, the Exchange compared the proposed new percentage parameters against only the current Rule 123D Mandatory Indications because these indications are more widely distributed via the SIP to market participants, and therefore more likely to be relied upon for purposes of assessing the opening price of a security on the Exchange. In addition, unlike Rule 15 Indications, a DMM is required to update Rule 123D Mandatory Indications, and thus this form of pre-opening indication is more likely to track to the actual opening price of a security.

[14] *See* NYSE Rule 48 Notice of Filing, *supra* note 7 at 70916.

By proposing to specify in its rules that the Applicable Price Range would be 10%, rather than 5%, when the market is more volatile, the Exchange would require DMMs to disseminate pre-opening indications in those securities experiencing the greatest price movement. Under current rules, the Exchange's only option when the overall market is volatile is to lift the requirement for pre-opening indications under Rule 48. The Exchange also proposes to use the 10% percentage parameter when reopening securities following a market-wide trading halt under Rule 80B. The Exchange believes that widening the parameters for pre-opening indications following a market-wide trading halt would be appropriate because the reason for the trading halt was market-wide volatility, and thus the reopening of securities would face similar pricing pressure as circumstances when there is pre-opening extreme market-wide volatility. The Exchange also proposes that it would have the authority to use the 10% Applicable Price Range when it is necessary or appropriate for the maintenance of a fair and orderly market. For example, if the E-mini S&P 500 Futures were not plus or minus 2% as of 9:00 a.m., but moved to that level between 9:00 and 9:30, it may be appropriate, for the maintenance of a fair and orderly market, to use widened percentage parameters.

To determine the percentage parameter that would be appropriate for trading days with extreme market-wide volatility, the Exchange reviewed NYSE trading data from August 24, 25, and 26, 2015 and assessed how many Rule 123D Mandatory Indications would have been required under the NYSE rules in place at that time, and how many pre-opening indications would have been required if a 5% and 10% percentage parameter were used on those days. Taking for example August 24, 2015, as set forth on Table 1 below, the NYSE data show that, had the NYSE not invoked Rule 48 lifting the requirement to publish Rule 123D Mandatory Indications, there would have been 638 securities (19% of securities) for which NYSE DMMs would have been required to publish Rule 123D Mandatory Indications. As set forth in Table 2 below, a 5% percentage parameter would have required 1,460 pre-opening indications (44% of securities) on NYSE on August 24, 2015, more than twice as many as under the current parameters. As noted above, the Exchange believes that this would be too many pre-opening indications for DMMs to process on a trading day without impacting their ability to timely open their assigned securities.

By contrast, as set forth in Table 2 below, a 10% percentage parameter would have required pre-opening indications in 278 securities (8.4% of securities) on NYSE on August 24, 2015. While this number is still higher than the number of pre-opening indications that would have been published on NYSE on an average trading day in October using the 5% percentage parameter (see above), the Exchange believes that it strikes the appropriate balance between providing additional pre-opening information to investors and enabling the DMM's to timely open their assigned securities. As set forth in more detail in Tables 1 and 2 below, August 24 represents an outlier, even for days when there has been extreme market-wide volatility. For other days in 2015 when the NYSE declared an extreme market-wide volatility under Rule 48, as set forth in Tables 1 and 2 below, applying a 10% parameter would not materially change the number of pre-opening indications being published.

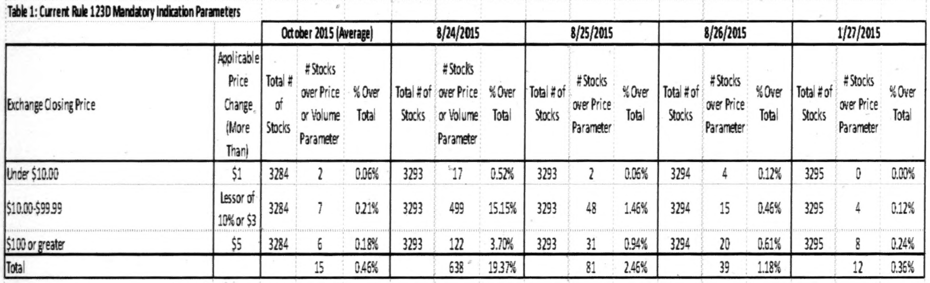

Table 1: Current Rule 123D Mandatory Indication Parameters

		October 2015 (Average)			8/24/2015			8/25/2015			8/26/2015			1/27/2015		
Exchange Closing Price	Applicable Price Change (More Than)	Total # of Stocks	# Stocks over Price or Volume Parameter	% Over Total	Total # of Stocks	# Stocks over Price or Volume Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total
Under $10.00	$1	3284	2	0.06%	3293	17	0.52%	3293	2	0.06%	3294	4	0.12%	3295	0	0.00%
$10.00-$99.99	Lessor of 10% or $3	3284	7	0.21%	3293	499	15.15%	3293	48	1.46%	3294	15	0.46%	3295	4	0.12%
$100 or greater	$5	3284	6	0.18%	3293	122	3.70%	3293	31	0.94%	3294	20	0.61%	3295	8	0.24%
Total			15	0.46%		638	19.37%		81	2.46%		39	1.18%		12	0.36%

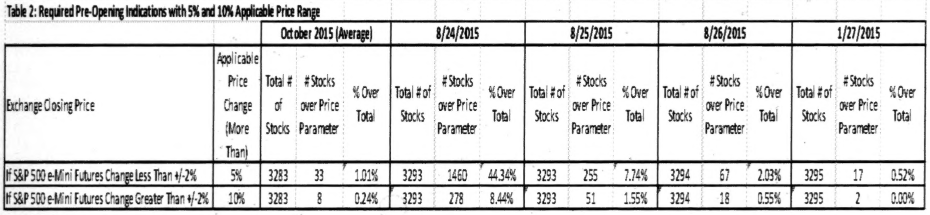

Table 2: Required Pre-Opening Indications with 5% and 10% Applicable Price Range

		October 2015 (Average)			8/24/2015			8/25/2015			8/26/2015			1/27/2015		
Exchange Closing Price	Applicable Price Change (More Than)	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total
If S&P 500 e-Mini Futures Change Less Than +/-2%	5%	3283	33	1.01%	3293	1460	44.34%	3293	255	7.74%	3294	67	2.03%	3295	17	0.52%
If S&P 500 e-Mini Futures Change Greater Than +/-2%	10%	3283	8	0.24%	3293	278	8.44%	3293	51	1.55%	3294	18	0.55%	3295	2	0.00%

Proposed Rule 15(e), entitled "Procedures for publishing a pre-opening indication," would set forth proposed procedures a DMM would use when publishing a pre-opening indication. As discussed below, these procedures are based on existing procedures currently set forth in Rule 123D, with specified differences.

Proposed Rule 15(e)(1) would provide that publication of pre-opening indications requires the supervision and approval of a Floor Governor.[15] This proposed rule change is based on the sixth paragraph of Rule 123D(b). The Exchange proposes a substantive change in that the proposed rule would require the supervision and approval of a Floor Governor, rather than supervision and approval of a Floor Official, as set forth in the current rule. The Exchange would also eliminate the requirement in Rule 123D that if a situation involves a bank or brokerage stock, the approval of an Executive Floor Governor is required, and if an Executive Floor Governor is unavailable, a Floor Governor or Senior Floor Governor's approval is required. The Exchange believes that requiring Floor Governor approval for all securities would involve the appropriate review by an experienced Floor official, while at the same time simplifying the approval process to require a single category of Floor Official to approve a pre-opening indication regardless of the type of security.[16]

Proposed Rule 15(e)(2) would provide that a pre-opening indication must be updated if the opening transaction would be at a price outside of a published pre-opening indication. Proposed Rule 15(e)(3) would further require that if a pre-opening indication is a spread wider than $1.00, the DMM should undertake best efforts to publish an updated pre-opening indication of $1.00 or less before opening the security, as may be appropriate for the specific security. Proposed Rules 15(e)(2) and (e)(3) are based, in part, on the second and third bullet points following the ninth paragraph of Rule 123D(b),[17] but with new rule text to simplify the requirements regarding updating pre-opening indications. With respect to proposed Rule 15(e)(3), for higher-priced securities, a pre-opening indication wider than $1.00 may be appropriate and it may not be necessary to narrow such indication any further, particularly since Opening Imbalance Information pursuant to Rule 15(c) (proposed Rule 15(g)) would also be disseminated regarding the security.

Proposed Rule 15(e)(4) would provide that, after publication of a pre-opening indication, the DMM must wait for the following minimum specified periods before opening a security:

- Proposed Rule 15(e)(4)(A) would provide that, when using the 5% Applicable Price Range specified in proposed Rule 15(d)(1), a minimum of three minutes must elapse between publication of the first indication and a security's opening. The rule would further provide that, if more than one indication has been published, a security may be opened one minute after the last published indication provided that at least three minutes have elapsed from the dissemination of the first indication. These first two sentences of proposed Rule 15(e)(4)(A) are based on rule text set forth in the twelfth and thirteenth paragraphs of current Rule 123D(b). Proposed Rule 15(e)(4)(A) would further provide that the DMM may open a security less than the required wait times after the publication of a pre-opening indication if the imbalance is paired off at a price within the Applicable Price Range. This proposed exception to the three-minute waiting requirement is new and is because the Exchange believes that, if equilibrium in price has been reached at a price within the Applicable Price Range, *i.e.,* at a price that would not have required a pre-opening indication in the first instance, there is no reason to require the DMM to further delay the opening of the security in an effort to attract offsetting interest.
- Proposed Rule 15(e)(4)(B) would provide that, when using the 10% Applicable Price Range specified in Proposed Rule 15(d)(2), a minimum of one minute must elapse between publication of the first indication and a security's opening and that if more than one indication has been published, a security may be opened without waiting any additional time. As discussed above, proposed Rule 15(d)(2) would provide for new percentage parameters for trading days with extreme market-wide volatility. Based on the analysis of NYSE trade data for August 24, 2015, even with the new percentage parameters, there is the potential for 278 pre-opening indications to be required on NYSE on an extremely volatile trading day. Because these pre-opening indications would be manually published by the DMM, the Exchange believes that eliminating additional wait times would enable the DMMs to facilitate a speedy opening for a security that has been subject to a pre-opening indication on days with extreme market-wide volatility.

Proposed Rule 15(e)(5) would provide that, if trading is halted for a non-regulatory order imbalance, a pre-opening indication must be published as soon as practicable after the security is halted. This proposed rule text is based on the first sentence of the third bulleted paragraph following the ninth paragraph in Rule 123D(b), with a proposed substantive difference that a pre-opening indication should be published "as soon as practicable," rather than "immediately," after a security is halted. The Exchange believes that the proposed approach provides for more flexibility for the DMM to assess the order imbalance and publish a pre-opening indication that takes into consideration all applicable factors.

Proposed Rule 15(e)(6) would set forth the requirements for pre-opening indications when reopening a security following a trading pause under Rule 80C.[18] Proposed Rule 15(e)(6)(A) would provide that a pre-opening indication may be published without prior Floor Governor approval. Proposed Rule 15(e)(6)(B) would provide that a pre-opening indication would not need to be updated before reopening the security, and the security may be reopened outside of any prior indication. Lastly, proposed Rule15(e)(6)(C) would provide that the reopening is not subject to the minimum waiting time requirements in Proposed Rule 15(e)(4). Proposed Rules 15(e)(6)(A)–(C) are based on Rule 80C(b)(2)(A), with non-substantive differences to use different rule text cross-references.

Proposed Rule 15(f), entitled "Temporary Suspension of Pre-Opening Indications," would provide in proposed Rule 15(f)(1) that if the CEO of the Exchange determines that a Floor-wide event is likely to impact the ability of DMMs to arrange for a fair and orderly opening or reopening and that absent such relief, operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend the requirement to publish pre-opening indications under Rule 15 prior to opening or reopening a security following a market-wide trading halt.[19]

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[15] Rule 46—Equities describes the different categories of Floor Officials, which are Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors, and Executive Floor Governors. Floor Governors are generally more senior members of the Trading Floor or qualified Exchange employees and are also empowered to perform any duty of a Floor Official.

[16] The Exchange would also be deleting the 14th through 16th paragraphs of Rule 123D(b) regarding Floor Official approval for "tape indications," which are Rule 123D Mandatory Indications. The Exchange believes that proposed Rule 15(e)(1) simplifies the approval process and obviates the need for this Rule 123D rule text.

[17] The second bullet following the ninth paragraph of Rule 123D(b) requires that the number of indications should increase in proportion to the anticipated disparity in the opening or reopening price, with increasingly definitive, "telescoped" indications when an initial narrow indication spread is impractical. The third bullet provides for similar requirements following a non-regulatory halt, and specifically that a final indication with a one point (one dollar) spread would be appropriate.

[18] Rule 80C sets forth the Exchange's rules to comply with the requirements of the Plan to Address Extraordinary Market Volatility submitted to the Commission pursuant to Rule 608 of Regulation NMS under the Act known as the Limit Up/Limit Down ("LULD") Plan.

Proposed Rule 15(f) is based in part on Rule 48, which provides that a qualified Exchange officer may declare an extreme market volatility condition and temporarily suspend the requirements for pre-opening indications.[20] Because the Exchange would be specifying new percentage parameters for pre-opening indications on trading days with market-wide volatility, the Exchange does not believe that it needs Rule 48 in its current form. While the Exchange expects that its other proposed changes to DMMs' requirements related to pre-opening indications will make it unlikely that a complete suspension of pre-opening indications would be required, the Exchange believes it would be prudent for the CEO of the Exchange to retain the authority to temporarily suspend the requirements to make pre-opening indications for events that it cannot currently predict. Accordingly, rather than refer to extreme market-wide volatility as in current Rule 48, proposed Rule 15(f)(1) would refer to a Floor-wide event that could impact the fair and orderly opening or reopening of securities more generally.

Proposed Rule 15(f)(2), which is based on Rule 48(c)(1)(A), would specify the range of factors that the CEO of the Exchange would be required to consider in making any determination to temporarily suspend the requirement for pre-opening indications.[21] In addition, similar to Rule 48(c)(1)(B) and 48(c)(1)(C), which requires the qualified Exchange officer to take its review "in consultation with relevant Exchange regulatory and operational employees that are officers of the Exchange, as appropriate" and to inform Commission staff as promptly as practicable, proposed Rules 15(f)(2)(B) and (C) would require the CEO to notify the CRO of the Exchange in making a determination under proposed Rule 15(f)(1) and inform Commission staff as promptly as practicable that pre-opening indications under Rule 15 have been temporarily suspended. Proposed Rule 15(f)(3), which is based on Rule 48(c)(4), would provide that a temporary suspension under Rule 15(f) would be in effect only for the trading day on which it was declared.[22] Finally, proposed Rule 15(f)(4) would provide that notwithstanding a temporary suspension of the requirement to publish pre-opening indications in a security under Rule 15, a DMM or the Exchange may publish a pre-opening indication for one or more securities. This proposed rule text, which is based in part on Rule 48(c)(5), would allow a DMM or the Exchange to publish a pre-opening indication, even if the rule were suspended.[23] Unlike Rule 48(c)(5), which specifies conditions when the DMM should still publish a pre-opening indication, proposed Rule 15(f)(3) would not require pre-opening indications, but rather, would allow them to be published even if the rule were temporarily suspended.

Because the Exchange has added new subsections to Rule 15, the Exchange proposes to renumber Rule 15(c) as Rule 15(g) and to add a header to this subsection of rule entitled "Opening Order Imbalance Information." In addition to re-designating the rule from Rule 15(c) to Rule 15(g), the Exchange proposes non-substantive differences to re-number the subsections of proposed Rule 15(g) to use the same numbering convention as proposed for proposed Rule 15(a)–(f), delete the phrase "the provisions of" in proposed Rule 15(g)(2)(B), and remove the reference to subparagraph (b) by deleting the phrase "or (b)."

The Exchange also proposes a substantive difference to change Rule 15(c)(3)(iii) (re-numbered as proposed Rule 15(g)(3)(C)) to increase the frequency with which the Exchange disseminates Order Imbalance Information[24] beginning at 9:20 a.m. ET. Currently, under Rule 15(c)(3)(iii), Order Imbalance Information is disseminated approximately every 15 seconds between 9:20 a.m. ET and the opening of trading in that security. The Exchange proposes to disseminate Order Imbalance Information approximately every 5 seconds between 9:20 a.m. ET and the opening of trading in that security. The Exchange believes that increasing the frequency with which Order Imbalance Information is disseminated would provide market participants with additional updated pre-opening information, thus promoting transparency for the opening transaction.[25]

Finally, the Exchange proposes to add new Supplementary Material .10 to Rule 15 providing that, unless otherwise specified in the proposed Rule,[26] references to an opening transaction include a reopening transaction following a trading halt or pause in a security. Currently, Rule 123D Mandatory Indications are required for both openings and reopenings. Because proposed Rule 15 indications would similarly be required for openings and reopenings following a halt or pause, the Exchange proposes to add Supplementary Material .10 to Rule 15.

DMM Automated Openings

As noted above, the process for publishing either Rule 15 Indications or Rule 123D Mandatory Indications is manual, and is generally followed by the DMM effecting the opening of a security manually rather than electronically. Consistent with this approach, the Exchange currently systemically blocks DMMs from opening a security electronically if the opening price would be outside of price parameters that are based on the price buckets and applicable price ranges specified in Rule 15(a). The Exchange similarly blocks DMMs from electronically opening a security if size of the opening transaction would be a significant volume, which similarly would indicate the potential need for manual oversight of the opening process.

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[19] Pursuant to Rule 1—Equities, the CEO of the Exchange may formally designate one or more qualified employees of Intercontinental Exchange, Inc. ("ICE") to act in place of any person named in a rule as having authority to act under such rule in the event the named person in the rule is unavailable to administer that rule.

[20] Rule 48(d) defines a "qualified Exchange officer" for purposes of Rule 48 as the CEO of ICE, or his or her designee, or the Chief Regulatory Officer ("CRO") of the Exchange, or his or her designee. The Exchange proposes to streamline its rules to specify that only the CEO of the Exchange would have the authority to temporarily suspend the requirement for pre-opening indications. However, pursuant to Rule 1—Equities, the CEO could delegate this authority to other qualified ICE employees.

[21] As provided for in Rule 48(c)(1)(A), these factors include volatility in the previous day's trading session, trading in foreign markets before the open, substantial activity in the futures market before the open, the volume of pre-opening indications of interest, evidence of pre-opening significant order imbalances across the market, government announcements, news and corporate events, and such other market conditions that could impact Floor-wide trading conditions.

[22] Rule 48(c)(4) provides that that a declaration of an extreme market volatility condition under Rule 48 shall be in effect only for the particular opening or reopen for the trading session on the particular day that the extreme market volatility condition if determined to exist.

[23] Rule 48(c)(5) provides that a declaration of an extreme market volatility condition shall not relieve DMMs from the obligation to make pre-opening indications in situations where the opening of a security is delayed for reasons unrelated to the extreme market volatility condition.

[24] Order Imbalance Information reflects real-time order imbalances that accumulate prior to the opening transaction on the Exchange and the price at which interest eligible to participate in the opening transaction may be executed in full. Order Imbalance Information disseminated pursuant to Rule 15(c) includes all interest eligible for execution in the opening transaction of the security in Exchange systems, *i.e.*, electronic interest, including Floor broker electronic interest, entered into Exchange systems prior to the opening. Order Imbalance Information is disseminated on the Exchange's proprietary data feeds. *See* Rule 15(c)(1).

[25] The Exchange also proposes to amend Rule 80C(b)(2)(A) to provide that the Order Imbalance Information disseminated during a Trading Pause would also be in approximately 5 second increments. The Exchange also proposes a non-substantive amendment to this rule text and to Rule 80C(b)(2) to add "-Equities" to the internal rule reference.

[26] *See, e.g.*, proposed Rules 15(d)(2) (referring only to reopenings following a market-wide trading halt under Rule 80B) and 15(e)(6) (specifying different procedures when reopening trading following a trading pause).

Because the DMM is not obligated to open a security electronically, the Exchange has not historically specified in its rules the parameters for when the DMM may effect an opening electronically.[27] However, following the events of the week of August 24, 2015, the Exchange believes that specifying in Exchange rules the conditions in which a DMM is permitted to open a security electronically would provide greater transparency in Exchange rules. The Exchange therefore proposes to amend Rule 123D(a) to specify when a DMM may effect an opening electronically.

In specifying parameters for when a DMM may effectuate an opening electronically, the Exchange proposes to adopt parameters and requirements that would be structured similarly to the proposed parameters for new Rule 15 pre-opening indications, as discussed above. Because Rule 123D(a)(1) is applicable to reopenings, the Exchange proposes to add to Rule 123D(a) that unless otherwise specified, references to an open or opening in Rule 123D(a) also mean a reopening following a trading halt or pause in a security. This proposed rule text is based on the last sentence of Rule 123D(a)(2).[28] As proposed, this text would be applicable to Rules 123D(a)(1) and (a)(2) in addition to Rules 123D(a)(3)–(6), as currently provided for in Rule 123D(a)(2). The Exchange proposes to delete the last sentence of Rule 123D(a)(2) as duplicative of the proposed new rule text. The Exchange also proposes to add language to paragraph (1) of Rule 123D(a) to provide for DMM responsibilities regarding the reopening process. As proposed, Rule 123D(a)(1) would explicitly state that it is the responsibility of each DMM to ensure that registered securities open as close to the end of a halt or pause, while at the same time not unduly hasty, particularly when at a price disparity from the last price on the Exchange.

The Exchange proposes new subsection numbering to Rule 123D(a)(1) to break out the third and fourth sentences of current Rule 123D(a)(1) to be proposed Rules 123D(a)(1)(A) and (B).[29] The Exchange proposes to add to proposed Rule 123D(a)(1)(B) that Exchange systems would not permit a DMM to open a security electronically if a DMM has manually entered Floor interest. This is how Exchange systems currently function and is similar to Rule 123C.10—Equities regarding when a DMM may close a security electronically.

The Exchange proposes to set forth the parameters for when a DMM may effect an opening electronically in new proposed Rules 123D(a)(1)(B)(i), (ii), and (iii):

- Proposed Rule 123D(a)(1)(B)(i) would provide that except under the conditions set forth in Rules 123D(a)(1)(B)(ii) and (iii), a DMM may not effect an opening electronically if; (a) the opening (but not reopening) transaction would be at a price more than 4% away from the Official Closing Price, as defined in Rule 123C(1)(e)—Equities, (b) the reopening transaction would be at a price more than 4% away from the last sale price on the Exchange; or (c) the matched volume for the opening transaction would be more than (1) 150,000 shares for securities with an average opening volume of 100,000 shares or fewer in the previous calendar quarter; or (2) 500,000 shares for securities with an average opening volume of over 100,000 shares in the previous calendar quarter. For purposes of this Rule, the calendar quarters will be based on a January 1 to December 31 calendar year.
- The Exchange believes that when reopening a security, the Official Closing Price from the prior day would no longer be a relevant reference price because the security has already opened for trading. Rather, because the security has been subject to a halt or pause before reopening, the Exchange believes that using the last sale price on the Exchange would be more representative of the most recent price of a security. A reopening price that would be more than 4% away from the last Exchange sale price demonstrates a level of price movement in a security during the halt or pause that warrants the manual price discovery process for the reopening. If the reopening price were to be within 4% away from the last Exchange sale price, that security likely has not experienced as much price movement, and therefore an electronic reopening may be more appropriate.
- Proposed Rule 123D(a)(1)(B)(ii) would provide that if as of 9:00 a.m. ET, the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures, or if the Exchange determines that it is necessary or appropriate for the maintenance of a fair and order market, a DMM could effect an opening electronically if the opening transaction would be at a price of up to 8% away from the Official Closing Price, as defined in Proposed Rule 123C(1)(e)—Equities, (for openings, but not reopenings) or the last sale price on the Exchange (for reopenings), without any volume limitations.
- Proposed Rule 123D(a)(1)(B)(iii) would provide that when reopening a security following a trading pause under Rule 80C or a market-wide halt under Rule 80B—Equities, if a pre-opening indication has been published in a security under Rule 15—Equities, a DMM may not reopen such security electronically if the reopening transaction would be at a price outside of the last-published pre-opening indication.
- The Exchange believes that because price volatility was likely the cause of such trading pause or halt, if the DMM publishes a pre-opening indication in a security for a reopening following such trading pause or halt, the reopening price should be within such pre-opening indication price range, regardless of whether the security is reopened manually or electronically. If the price moves away from the last pre-opening indication, the DMM should publish a new pre-opening indication to provide notice of the new price range.[30] Because the DMM would need to reopen a security within such price indication range, the Exchange believes it is appropriate to prohibit a DMM from reopening electronically if the reopening price were to be outside of the last-published pre-opening indication.

Similar to the new Applicable Price Ranges for pre-opening indications proposed in Rule 15(d) above, the

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[27] Rule 123D does not require DMMs to open a security electronically; a DMM may determine that in the particular circumstances for a security, manually opening the security may be warranted, even if the price would be within the Applicable Price Range. For example, if a Floor broker has represented an order in the Crowd, the DMM will open a security manually.

[28] *See* Rule 123D(a)(2) ("Unless otherwise specified, references to an open or opening in paragraphs (a)(3)–(a)(6) of this Rule also mean a reopening following a trading halt or pause."). *See also* proposed Supplementary Material .10 to Rule 15—Equities ("Unless otherwise specified in this Rule, references to an opening transaction include a reopening transaction following a trading halt or pause in a security.")

[29] The Exchange also proposes a non-substantive amendment to change the term "stock" to "security" and to fix a typographical error to add the letter "m" before the word "may."

[30] *See* proposed Rule 15(e)(2) (a pre-opening indication must be updated if the opening transaction would be at a price outside of a published pre-opening indication).

Exchange proposes to use a single percentage parameter for all securities, regardless of price. The Exchange also proposes to double those percentage parameters on days with extreme market-wide volatility, and would use the same standard for determining whether there is market-wide volatility as is proposed in Rule 15(d)(2), described above. Because the Exchange continues to believe that, if a pre-opening indication has been published, a security is better served if a DMM effects a manual opening, the Exchange proposes to apply percentage parameters to DMM automated openings that are tighter than the requirements for publishing a pre-opening indication. In other words, if a pre-opening indication would be required under proposed Rule 15, the DMM would not be permitted to effect an opening electronically. To achieve this goal, the Exchange proposes that the percentage parameter on a regular trading day for DMM automated opens should be one percent lower than the percentage parameter for pre-opening indications on a regular trading day. And as with pre-opening indications, on a day with extreme market-wide volatility, the applicable percentage would be doubled.

The Exchange believes that the proposed conditions for when a DMM may effect an opening electronically would reduce the number of manual openings and enable more securities to open closer to 9:30 a.m. ET, both on regular trading days and on extremely volatile trading days such as August 24, 2015.

Tables 3 through 5 below illustrate how many securities would not be eligible for a DMM to effect an opening electronically when applying the current and proposed percentage and volume parameters to NYSE trade data from October 2015 and NYSE trade data from August 24, 2015.

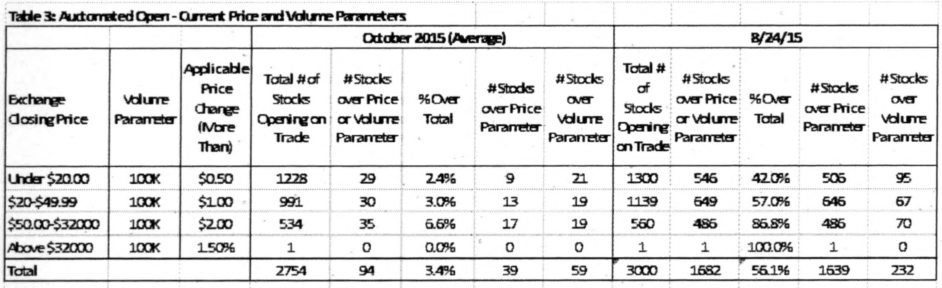

Table 3: Automated Open - Current Price and Volume Parameters

			October 2015 (Average)					8/24/15				
Exchange Closing Price	Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter
Under $20.00	100K	$0.50	1228	29	2.4%	9	21	1300	546	42.0%	506	95
$20-$49.99	100K	$1.00	991	30	3.0%	13	19	1139	649	57.0%	646	67
$50.00-$32000	100K	$2.00	534	35	6.6%	17	19	560	486	86.8%	486	70
Above $32000	100K	1.50%	1	0	0.0%	0	0	1	1	100.0%	1	0
Total			2754	94	3.4%	39	59	3000	1682	56.1%	1639	232

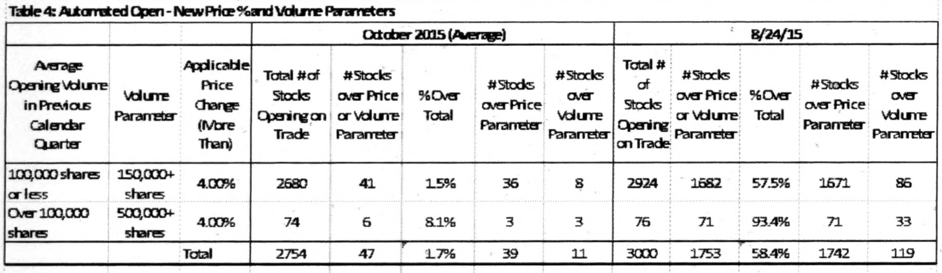

Table 4: Automated Open - New Price % and Volume Parameters

			October 2015 (Average)					8/24/15				
Average Opening Volume in Previous Calendar Quarter	Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter
100,000 shares or less	150,000+ shares	4.00%	2680	41	1.5%	36	8	2924	1682	57.5%	1671	86
Over 100,000 shares	500,000+ shares	4.00%	74	6	8.1%	3	3	76	71	93.4%	71	33
		Total	2754	47	1.7%	39	11	3000	1753	58.4%	1742	119

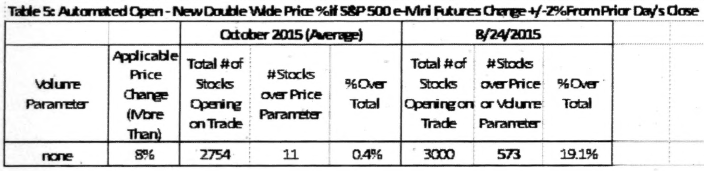

Table 5: Automated Open - New Double Wide Price % if S&P 500 e-Mini Futures Change +/-2% From Prior Day's Close

		October 2015 (Average)			8/24/2015		
Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price Parameter	% Over Total	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total
none	8%	2754	11	0.4%	3000	573	19.1%

For example, as set forth in Table 3, using current price parameters and a 100,000 share volume parameter, in October 2015, 94 securities (13.4% of securities) on NYSE on average each day were not eligible to be opened by the DMM electronically. As demonstrated in Table 4, using the proposed 4% price and tiered volume parameters, a comparable 47 securities (1.7% of securities) on NYSE on average in October would not have been eligible to be opened by the DMM electronically.

With respect to the proposed volume parameters, the Exchange believes that having a parameter tied to higher-than-average opening volume in a security would better reflect whether opening electronically would be appropriate. For example, as the data show in Table 4, on NYSE, there were 74 securities averaging daily opening volume over 100,000 shares in the previous quarter (3Q15) and three of those securities had opening volume of over 500,000 shares on an average daily basis in October. The Exchange believes that if a security has a higher-than-average opening volume on a quarterly basis without any corresponding price dislocation, then the volume of shares trading on the opening for such securities is not representative of any volatility for that security, but rather, is a regular state of affairs that does not require a high-touch opening managed by a DMM on the trading Floor. Rather, such securities would benefit from being available for the DMM to open electronically in order to promote a fair and orderly opening at or near the open of trading. The Exchange further believes that securities with an average daily volume of over 500,000 shares at the open are the types of securities that most warrant the

DMM's high touch. Specifically, such large-sized openings are likely to be indicative of block-sized trades participating in the opening. The Exchange's high-touch model allows for greater price discovery for such securities by leveraging the Exchange's Floor broker agency community to solicit block-sized interest to participate in the opening.

As with pre-opening indications, the Exchange proposes to double the percentage parameter on trading days with extreme market-wide volatility and eliminate the volume parameter. As illustrated in Table 5, doubling the percentage parameter and eliminating the volume parameters would allow DMMs to open most NYSE securities electronically even during extreme market-wide volatility. As NYSE trade data from August 24, 2015 set forth in Table 3 illustrates, the current percentage parameters restricted DMMs from opening 1,753 securities electronically, which represents 58.4% of securities on NYSE.[31] As set forth in Table 5, applying the proposed 8% percentage parameter would have allowed DMMs to open all but 573 securities electronically, which represents 19.1% of the securities traded on NYSE.

The Exchange also proposes to add a new paragraph (c) to Rule 123D entitled "Temporary Suspension of DMM Automated Opening Limitations or Floor Official Approval." Similar to proposed Rule 15(f), if the CEO of the Exchange determines that a Floor-wide event is likely to have an impact on the ability of DMMs to arrange for a fair and orderly opening or reopening following a market-wide trading halt at the Exchange and that, absent relief, the operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend the prohibition on a DMM opening a security electronically if the opening transaction would be more than the price or volume parameters specified in proposed Rule 123D(a)(1)(B). This would be a new suspension authority that relates to the proposed new price and volume parameters for when a DMM may open a security electronically. The Exchange believes that having this temporary suspension authority would be appropriate for situations if the DMM is unable to open a security manually, either due to unavailability of 11 Wall Street facilities or because of systems or technical issues with Floor-based tools for manually opening a security.

Proposed Rule 123D(c) would also provide that if the CEO of the Exchange determines that a Floor-wide event is likely to have an impact on the ability of DMMs to arrange for a fair and orderly opening or reopening following a market-wide trading halt at the Exchange, and that absent relief, the operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend (i) the prohibition on a DMM opening a security electronically if the opening transaction will be more than the price or volume parameters specified in proposed Rule 123D(a)(1)(B); or (ii) the need under Rule 123D(b) for prior Floor Official approval to open or reopen a security following a market-wide trading halt. This proposed rule change is similar to authority in current Rule 48, which permits a qualified Exchange officer to temporarily suspend the need for prior Floor Official or prior NYSE Floor operations approval to open or reopen a security following a market-wide trading halt. While the Exchange expects that its other proposed changes to Rule 123D would make it unlikely that a complete suspension of prior Floor Official approval would be required, the Exchange believes it would be prudent for the CEO of the Exchange to retain the authority temporarily suspend such requirements for events that it cannot currently predict. The Exchange also proposes a new temporary suspension that correlates to the proposed new price and volume parameters for when a DMM may open a security electronically. The Exchange expects that this relief would be required if 11 Wall Street facilities were unavailable and DMMs would be required to open all securities remotely, and thus electronically.

Proposed Rule 123D(c)(2)–(3) are nearly identical to proposed Rule 15(f)(1)–(3), as described in greater detail above, with changes only to address that this proposed rule relates to the temporary suspension of the requirements for specified paragraphs of Rule 123D. Proposed Rule 123D(c)(2)–(3) is based on the same provisions of Rule 48 that proposed Rule 15(f)(2)–(4) is based on, which is discussed in greater detail above.

The miscellaneous and technical amendments proposed to Rule 123D are as follows:

- The Exchange proposes to amend Rule 123D(a)(5) (Pre-Opening Information) to change the citation to Rule 15(c) to 15(g) based on the proposed changes to Rule 15, described above, and delete the word "either" and the references to Rule 123D.
- The Exchange proposes to delete the phrase "Halts in Trading" from the heading of Rule 123D(b).
- Also in Rule 123D(b), the Exchange proposes to delete the text relating to the dissemination of mandatory indications beginning with the sentence "If an unusual situation exists, such as a large order imbalance, tape indications should be disseminated, including multiple indications if appropriate with the supervision of a Floor Official" through and including the sentence "An Executive Floor Governor or Floor Governor should be consulted in any case where there is not complete agreement among the Floor Officials participating in the discussion." This rule text all pertains to Rule 123D Mandatory indications, which, as discussed above, would be governed by proposed Rule 15.
- The Exchange proposes to add a new heading (d) entitled "Halts in Trading" before the sentence "Once trading has commenced, trading may only be halted with the approval of a Floor Governor or two Floor Officials" in current Rule 123D(b) and change current heading (c) (Equipment Changeover) to (e).
- Finally, in current Rule 123D(c) (proposed Rule 123D(e)), to reflect that all information relating to pre-opening indications, including the Applicable Price Ranges and Reference Prices, are now described in Rule 15, the Exchange proposes to delete the phrase "a significant order imbalance (one which would result in a price change from the last sale of one point or more for stocks under $10, the lesser of 10% or three points for $10—$99.99 and five points if $100 or more—unless a Floor Governor deems circumstances warrant a lower parameter) develops" and add the phrase "a pre-opening indication would be required to be published" in its place.

Rule 48

The Exchange proposes to delete Rule 48 in its entirety. As discussed above, the Exchange is proposing changes to Rules 15 and 123D that it believes will allow DMMs to publish pre-opening indications in a manageable number of securities, even on days of high volatility, which would promote transparency regarding opening prices at the Exchange. In addition, and as described above, the Exchange is incorporating into Rules 15 and 123D authority for the CEO of the Exchange to temporarily suspend the requirement to publish pre-opening indications, the pricing and volume limitations for a

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[31] On August 24, 2015, DMMs also chose not to open securities electronically, even if they would have been priced within the current price parameters.

DMM to open a security electronically, and for a DMM to obtain Floor Official approval under Rule 123D(b) when opening or reopening a security, if the CEO of the Exchange determines that such relief is necessary to the ability of DMMs to open the securities and to the operation of the Exchange. Accordingly, the Exchange believes that the Rule 48 is no longer necessary.

Conforming and Technical Amendments—Rules 80C and 9217

Rule 80C

The Exchange proposes conforming amendments Rule 80C(b)(2), which governs a Trading Pause under the LULD Plan.

First, Rule 80C(b)(2) requires that the Exchange re-open the security in a manner similar to the procedures set forth in Rule 123D following a Trading Pause (as defined therein). The Exchange proposes to add a reference to Rule 15 to Rule 80C(b)(2), so that the requirement to re-open would be in a manner similar to Rules 15 and 123D.

Second, the Exchange proposes to delete subdivision (A) of Rule 80C(b)(2) in its entirety and mark the deleted text as "Reserved." As noted above, the requirements for reopening a security following a trading pause set forth in Rule 80C would be codified in proposed Rule 15(d)(6).

Rule 9217

The Exchange also proposes to amend Rule 9217, which sets forth the list of rules under which a member organization or covered person may be subject to a fine under a minor rule violation plan as set forth in Rule 9216(b). Rule 9217 permits a summary fine for violations of Rule 123D requirements for DMMs relating to openings, reopenings, delayed openings, trading halts, and tape indications. The Exchange proposes to delete the clause "tape indications" to reflect elimination of mandatory indications from Rule 123D. The Exchange believes this proposed change would add transparency and clarity to the Exchange's rules.

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Because of the technology changes associated with the proposed rule change, the Exchange will announce by Trader Update the implementation date of the changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[32] in general, and furthers the objectives of Section 6(b)(5) of the Act,[33] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

The Exchange believes that streamlining and consolidating pre-opening indications into a single rule (Rule 15) from two (Rules 15 and 123D) would remove impediments to and perfect the mechanism of a free and open market because it would set forth in a single rule the requirements for pre-opening indications, thereby promoting transparency by using consistent terminology for rules governing equities trading and ensuring that members, regulators, and the public can more easily navigate the Exchange's rulebook.

The Exchange believes that adopting new single-wide (5% change) and double-wide (10% change if S&P 500 futures move 2%) percentage parameters for the publication of pre-opening indications would remove impediments to and perfect the mechanism of a free and open market by requiring issuance of more pre-opening indications than currently during times of market stress, thereby increasing the amount of information available in the pre-market and improving the quality of price discovery at the opening. The proposed rule therefore promotes just and equitable principles of trade because it would expand the amount of pre-opening information available to the marketplace, thereby promoting transparency. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

The Exchange believes that amending Rule 123D to specify when a DMM may effect an opening electronically would remove impediments to and perfect the mechanism of a free and open market by promoting transparency in Exchange rules regarding under what circumstances a DMM may effect an opening electronically. The Exchange believes that the proposed parameters for when a DMM may open a security electronically, which would be 4% on regular trading days and doubled to 8% in times of market stress, would remove impediments to and perfect the mechanism of a free and open market by reducing the number of manual openings and enabling more securities to open closer to 9:30 a.m. ET on extremely volatile trading days, thereby providing customers and the investing public with greater certainty of a timely open in circumstances of extreme market stress. The Exchange further believes that the proposal would advance the efficiency and transparency of the opening process, thereby fostering accurate price discovery at the open of trading. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

The Exchange believes that using the last Exchange sale price as a reference price for reopenings would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because using the last sale price on the Exchange would be more representative of the most recent price of a security from before the halt or pause. In addition, the Exchange believes that if a security were to reopen more than 4% (or 8% on a more volatile trading day) from that reference price, such reopening would likely benefit from the manual price discovery process. The Exchange also believes that it would remove impediments to and perfect the mechanism of a free and open market to provide that a DMM may reopen a security electronically if the reopening transaction would be at a price outside of the last-published pre-opening indication when reopening a security following a trading pause under Rule 80C or a market-wide halt under Rule 80B and a pre-opening indication has been published under Rule 15.

The Exchange believes that deleting Rule 48 and moving the applicable provisions to Rules 15 and 123D would remove impediments to and perfect the mechanism of a free and open market by reducing reliance on Rule 48 during extremely volatile trading days. Rather, as proposed, the need for the CEO of the Exchange to temporarily suspend either pre-opening indications or the need for prior Floor Official approval before opening or reopening a security would be under more narrow circumstances of when a Floor-wide event would impair the Exchange's ability to conduct a fair and orderly open or reopening. As discussed above, the proposed amendments to Rule 15 and 123D to provide for parameters on days with extreme market-wide volatility would obviate the need for the current Rule 48 ability to lift the requirements for pre-opening indications or prior Floor Official approval during extreme market-wide volatility. The Exchange further believes that the proposal would advance the efficiency and transparency of the opening process, thereby fostering accurate price discovery at the open of trading. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

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[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78f(b)(5).

The Exchange believes that making corresponding conforming changes to Rules 80C and 9217 would remove impediments to and perfects the mechanism of a free and open market by reducing potential confusion and adding transparency and clarity to the Exchange's rules, thereby ensuring that members, regulators and the public can more easily navigate and understand the Exchange's rulebook.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather promote greater efficiency and transparency at the open of trading on the Exchange. The Exchange believes the proposed rule change will ease a burden on competition by providing for similar standards for the opening process on the Exchange as have been approved for the NYSE, which currently operates on the same trading platform as the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[34] and Rule 19b–4(f)(6) thereunder.[35] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[36] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[37] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposed rule change is based on the approved rules of the NYSE and immediate effectiveness would enable the Exchange to implement changes to its rules that are designed to promote efficiency and transparency in the opening process. It would also enable the Exchange to implement the proposed changes to its opening process at the same time as similar changes are being implemented on the NYSE, which the Exchange believes would promote the protection of investors and the public interest. In addition, because the technology is ready for both this proposed rule change and the changes described in the NYSE Approval Order, the Exchange believes that waiver of the operative delay will allow for the Exchange to implement the approved changes to the opening process, without delay, at the same time that it implements the same changes to the NYSE rules. The Commission believes that the proposed rule change is consistent with the protection of investors and the public interest, because the proposal is reasonably designed to promote efficiency and transparency in the opening process, and because it would allow the proposal to be implemented concurrently with the parallel changes to the NYSE rules that have already been approved by the Commission. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[38]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[39] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–79 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–79. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–79 and should be submitted on or before September 21, 2016.

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[34] 15 U.S.C. 78s(b)(3)(A).

[35] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[36] 17 CFR 240.19b–4(f)(6).

[37] 17 CFR 240.19b–4(f)(6)(iii).

[38] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[39] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20880 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78694; File No. SR–BX–2016–047]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Short Term Option Series Program

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 25, 2016, NASDAQ BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Short Term Option Series Program to allow Wednesday expirations for SPY options.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqbx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BX Rules at Chapter I, Section 1(a)(60) and Chapter IV, Section 6 at Commentary .07 to expand the Short Term Option Series Program to permit the listing and trading of options with Wednesday expirations.

Currently, under the Short Term Option Series Program, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire ("Short Term Option Series"). The Exchange is now proposing to amend its rule to permit the listing of options expiring on Wednesdays. Specifically, the Exchange is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of options on the SPDR S&P 500 ETF Trust (SPY) to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire ("Wednesday SPY Expirations").[3] The proposed Wednesday SPY Expiration series will be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detail below. The Exchange notes that having Wednesday expirations is not a novel proposal. Specifically, BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[4]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing the Exchange from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange will be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion will not apply with Wednesday SPY Expirations and standard monthly options because they will not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week.

Under the proposed Wednesday SPY Expirations, the Exchange may list up to five consecutive Wednesday SPY Expirations at one time. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is the same listing procedure as Short Term Option Series that expire on Fridays. This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations will be the same as those for the current Short Term Option Series. Specifically, the Wednesday SPY Expirations will have $0.50 strike intervals.

Currently, for each Short Term Option Expiration Date,[5] the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges.[6] The thirty (30) series restriction shall apply to Wednesday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays.

As is the case with current Short Term Option Series, the Wednesday SPY Expiration series will be P.M.-settled. The Exchange does not believe that any market disruptions will be encountered with the introduction of

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[40] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* BX Rule Chapter IV, Section 6 at Commentary .07.

[4] *See* Securities Exchange Act Release No. 78668 (SR–BOX–2016–28) (pending publication in the **Federal Register**).

[5] BX may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* BX Rule Chapter IV, Section 6 at Commentary .07.

[6] *See* BX Rule Chapter IV, Section 6 at Commentary .07.

P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange is also amending the definition of Short Term Option Series to make clear that it includes Wednesday expirations.[7] Specifically, the Exchange is amending the definition to expand Short Term Option Series to those listed on any Tuesday or Wednesday and that expire on the Wednesday of the next business week. If a Tuesday or Wednesday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday or Wednesday. The Exchange believes that the introduction of Wednesday SPY Expirations will provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner. Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series. Also, the Exchange notes that BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that having Wednesday expirations is not a novel proposal, BOX has received approval to list Wednesday expirations for SPY options.[11] The Exchange does not believe the proposal will impose any burden on intra-market competition, as all market participants will be treated in the same manner. Additionally, the Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents the other options exchanges from proposing similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[15] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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[7] *See* proposed Chapter I, Section 1(a)(60).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See* supra, note 4.

[11] *See* supra, note 4.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* note 4.

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BX–2016–047 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–047. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–047 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20961 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78683; File No. SR–FINRA–2015–056]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change To Adopt FINRA Rule 2030 and FINRA Rule 4580 To Establish "Pay-To-Play" and Related Rules

August 25, 2016.

I. Introduction

On December 16, 2015, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt FINRA Rules 2030 (Engaging in Distribution and Solicitation Activities with Government Entities) and 4580 (Books and Records Requirements for Government Distribution and Solicitation Activities) to establish "pay-to-play"[3] and related rules that would regulate the activities of member firms that engage in distribution or solicitation activities for compensation with government entities on behalf of investment advisers. Member firms serving this role—sometimes referred to as "placement agents" or "solicitors" (collectively referred to herein as "placement agents")—assist investment advisers with obtaining advisory business from such entities. In this context, pay-to-play has historically presented a problem, including when investment advisers retain placement agents who have made contributions to government officials who are responsible for, or can influence the outcome of, the selection process for investment advisers. When investment advisers are chosen on the basis of a placement agent's political contributions, rather than on, for example, the adviser's merit, performance, or costs, the market and selection process for advisers becomes distorted. Ultimately, pay-to-play harms investors and the public interest if government entities, including public pension plans, and their beneficiaries receive inferior services or pay higher fees.

The proposed rule change was published for comment in the **Federal Register** on December 30, 2015.[4] The Commission received ten comment letters, from nine different commenters, in response to the Notice.[5] On February 8, 2016, FINRA extended the time period by which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to March 29, 2016.[6] On March 28, 2016, FINRA filed a letter with the Commission stating that it considered the comments received by the Commission in response to the Notice, and that FINRA is not intending to make changes to the proposed rule text in response to the comments.[7]

On March 29, 2016, pursuant to delegated authority, the Commission issued an order instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change, and solicited additional comment.[9] The Commission received an additional four comments regarding the proceedings,[10] including two letters requesting an opportunity to make an oral presentation in the proceedings.[11] On July 6, 2016, FINRA submitted a letter responding to all comments and to the Order Instituting Proceedings.[12] On June 21, 2016, FINRA extended the time period by which the Commission must determine whether to approve or disapprove the proposed rule change to August 26, 2016.[13]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] "Pay-to-play practices," "play-to-play arrangements" or "play-to-play activities," as referred to throughout this order, typically involve a person making cash or in-kind political contributions (or soliciting or coordinating others to make such contributions) to help finance the election campaigns of state or local officials or bond ballot initiatives as a *quid pro quo* for the receipt of government contracts.

[4] *See* Exchange Act Rel. No. 76767 (Dec. 24, 2015), 80 FR 81650 (Dec. 30, 2015) (File No. SR–FINRA–2015–056) ("Notice").

[5] *See* Letters from David Keating, President, Center for Competitive Politics ("CCP"), dated Jan. 20, 2016 ("CCP Letter 1"); Clifford Kirsch and Michael Koffler, Sutherland Asbill & Brennan LLP, for the Committee of Annuity Insurers ("CAI"), dated Jan. 20, 2016 ("CAI Letter 1"); Clifford Kirsch and Michael Koffler, Sutherland Asbill & Brennan LLP, for the CAI, dated Feb. 5, 2016 ("CAI Letter 2"); David T. Bellaire, Executive Vice President and General Counsel, Financial Services Institute ("FSI"), dated Jan. 20, 2016 ("FSI Letter 1"); Tamara K. Salmon, Assistant General Counsel, Investment Company Institute ("ICI"), dated Jan. 20, 2016 ("ICI Letter"); Patrick J Moran, Esq., dated Dec. 29, 2015 ("Moran Letter"); Gary A. Sanders, Counsel and Vice President, National Association of Insurance and Financial Advisors ("NAIFA"), dated Jan. 20, 2016 ("NAIFA Letter"); Judith M. Shaw, President, North American Securities Administrators Association, Inc. ("NASAA"), dated Jan. 20, 2016 ("NASAA Letter"); Hugh D. Berkson, President, Public Investors Arbitration Bar Association ("PIABA"), dated Jan. 20, 2016 ("PIABA Letter"); and H. Christopher Bartolomucci and Brian J. Field, Bancroft PLLC, for the New York Republican State Committee and the Tennessee Republican Party ("State Parties"), dated Jan. 20, 2016 ("State Parties Letter 1"). The comment letters filed with the Commission in connection with the proposed rule change are available at: *http://www.sec.gov/comments/sr-finra-2015-056/finra2015056.shtml*.

[6] *See* Letter from Victoria Crane, Associate General Counsel, FINRA, to Lourdes Gonzalez, Assistant Chief Counsel—Sales Practices, Division of Trading and Markets, Commission, dated Feb. 8, 2016.

[7] *See* Letter from Victoria Crane, Associate General Counsel, FINRA, to Brent J. Fields, Secretary, Commission, dated Mar. 28, 2016 ("FINRA Response Letter 1").

[8] 15 U.S.C. 78s(b)(2)(B).

This order approves the rule change as proposed. Section II provides an overview of the rule and summarizes the rule as described by FINRA in its filing and as published in the Notice, Section III is a summary of the comments received and FINRA's responses, and Section IV contains the Commission's findings in approving the proposal.

II. Description of the Proposed Rule Change [14]

As described more fully in the Notice, FINRA modeled proposed Rule 2030 [15] on the Commission's Rule 206(4)–5 under the Investment Advisers Act of 1940 ("Advisers Act"), which addresses pay-to-play practices by investment advisers (the "SEC Pay-to-Play Rule").[16] The SEC Pay-to-Play Rule, in part, prohibits any investment adviser covered under the rule [17] or any of its covered associates from providing or agreeing to provide, directly or indirectly, payment to any person to solicit a government entity for investment advisory services on behalf of such investment adviser unless such person is a "regulated person," [18] as defined under the rule, or an executive officer, general partner, managing member, or employee of the investment adviser.[19] A "regulated person," as defined in the SEC Pay-to-Play Rule, includes a registered broker-dealer, provided that: (a) FINRA rules prohibit member firms from engaging in distribution or solicitation activities if certain political contributions have been made to certain public officials; and (b) the Commission finds, by order, that such rules impose substantially equivalent or more stringent restrictions on member firms than the SEC Pay-to-Play Rule imposes on investment advisers and that such rules are consistent with the objectives of the SEC Pay-to-Play Rule.[20]

In light of this regulatory framework, FINRA proposed its own pay-to-play rule to enable its member firms to continue to engage in distribution and solicitation activities for compensation with government entities on behalf of investment advisers, while subjecting its member firms to appropriate safeguards that will discourage them from engaging in pay-to-play practices.[21] Because one of the objectives of FINRA's proposal is to satisfy the "regulated person" definition in the SEC Pay-to-Play Rule, the elements of and terms used in FINRA's proposal are substantially equivalent to and consistent with the objectives of the SEC Pay-to-Play Rule.[22] As discussed below, this threshold objective precludes many of the modifications proposed by commenters given that a more permissive FINRA proposal would not meet the stringency requirements of the SEC Pay-to-Play Rule. FINRA believes that its proposed rule would establish a comprehensive regime to regulate the activities of its member firms that engage in distribution or solicitation activities with government entities on behalf of investment advisers, and would impose substantially equivalent restrictions on FINRA member firms engaging in distribution or solicitation activities to those that the SEC Pay-to-Play Rule imposes on investment advisers.[23]

Furthermore, FINRA's proposed Rule 4580 would impose recordkeeping requirements on FINRA member firms in connection with its pay-to-play rule that would allow examination of member firms' books and records for compliance with Rule 2030.[24] FINRA believes that proposed Rule 4580 is consistent with similar recordkeeping requirements imposed on investment advisers in connection with the SEC Pay-to-Play Rule.[25]

The following is an overview of the key provisions in FINRA's proposed rules, as described by FINRA in the Notice.

A. Proposed Rule 2030(a): Limitation on Distribution and Solicitation Activities

Proposed Rule 2030(a) would prohibit a covered member from engaging in distribution or solicitation activities for compensation with a government entity on behalf of an investment adviser that provides or is seeking to provide investment advisory services to such government entity within two years after a contribution to an official of the government entity is made by the covered member or a covered associate, including a person who becomes a covered associate within two years after the contribution is made.[26] FINRA states that the terms and scope of the prohibitions in proposed Rule 2030(a) are modeled on the SEC Pay-to-Play Rule.[27] According to FINRA, the two-year time-out period is intended to discourage covered members from participating in pay-to-play practices by requiring a cooling-off period during which the effects of a political contribution on the selection process can be expected to dissipate.[28]

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[9] *See* Securities Exchange Act Release No. 77465 (Mar. 29, 2016), 81 FR 19260 (Apr. 4, 2016) ("Order Instituting Proceedings").

[10] *See* Letters from David T. Bellaire, Executive Vice President and General Counsel, FSI, dated Apr. 27, 2016 ("FSI Letter 2"); Jason Torchinsky, Holtzman Vogel Josefiak Torchinsky PLLC, on behalf of the Georgia Republican Party and the State Parties, dated April 12, 2016, filed April 21, 2016 ("State Parties Letter 2"); Allen Dickerson, Legal Director, CCP, dated April 21, 2016 ("CCP Letter 2"); Allen Dickerson, Legal Director, CCP, dated April 15, 2016 ("CCP Letter 3").

[11] *See* CCP Letter 2; State Parties Letter 2. The Commission denied both requests. *See* Letter from Brent J. Fields, Secretary, Commission, to Allen Dickerson, Legal Director, CCP dated July 11, 2016; Brent J. Fields, Secretary, Commission, to Jason Torchinsky, Holtzman Vogel Josefiak Torchinsky PLLC, on behalf the State Parties, dated July 11, 2016.

[12] *See* Letter from Victoria Crane, Associate General Counsel, FINRA, to Brent J. Fields, Secretary, Commission, dated July 6, 2016 ("FINRA Response Letter 2"). Both of FINRA's Responses Letters are available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA, and at the Commission's Public Reference Room.

[13] *See* Letter from Victoria Crane, Associate General Counsel, FINRA, to Lourdes Gonzalez, Assistant Chief Counsel—Sales Practices, Division of Trading and Markets, Commission, dated June 21, 2016.

[14] The proposed rule change, as described in Item II, is excerpted, in part, from the Notice, which was substantially prepared by FINRA. *See supra* note 4. A more detailed description of the proposed rule change is in the Notice.

[15] *See* Notice, 80 FR at 81650–51 (citing Advisers Act Release No. 3043 (July 1, 2010), 75 FR 41018 (July 14, 2010) (Political Contributions by Certain Investment Advisers) ("SEC Pay-to-Play Rule Adopting Release")).

[16] FINRA also published the proposed rule change in *Regulatory Notice* 14–50 (Nov. 2014) ("*Regulatory Notice* 14–50") and sought comment on the proposal. FINRA states that commenters were generally supportive of the proposed rule change, but also expressed some concerns. As such, FINRA revised the proposed rule change as published in *Regulatory Notice* 14–50 in response to those comments. As described more fully in the Notice, FINRA believes that the revisions it made more closely align FINRA's proposed rule with the SEC Pay-to-Play Rule and should help reduce cost and compliance burden concerns raised by commenters. *See* Notice, 80 FR at 81651 n.16.

[17] The SEC Pay-to-Play Rule applies to investment advisers registered or required to be registered with the Commission, foreign private advisers that are unregistered in reliance on Section 203(b)(3) of the Advisers Act, and exempt reporting advisers as defined in Rule 204–4(a) under the Advisers Act. *See* 17 CFR 275.206(4)–5(a)(2).

[18] *See* Notice, 80 FR at 81650 n.6, 81656. *See also* 17 CFR 275.206(4)–5(a)(2)(i)(A).

[19] *See* 17 CFR 275.206(4)–5(a)(2)(i)(B) (or, in each case, a person with a similar status or function to an executive officer, general partner, or managing member of the investment adviser).

[20] *See* Notice, 80 FR at 81650 n.6 (citing 17 CFR 275.206(4)–5(f)(9)). The definition of "regulated person" also includes SEC-registered investment advisers and SEC-registered municipal advisors, subject to specified conditions. The Commission amended the SEC Pay-to-Play Rule to add SEC-registered municipal advisors to the definition of "regulated persons." *See* Rules Implementing Amendments to the Investment Advisers Act of 1940, Investment Advisers Act Rel. No. 3221 (June 22, 2011), 76 FR 42950 (July 19, 2011).

[21] *See* Notice, 80 FR at 81651, 81656.

[22] On August 25, 2016, the Commission issued a notice stating that it intends to issue an order pursuant to Section 206 of the Advisers Act and SEC Pay-to-Play Rule 206(4)–5 finding that FINRA's proposed Rule 2030 (i) imposes substantially equivalent or more stringent restrictions on broker-dealers than the SEC Pay-to-Play Rule imposes on investment advisers and (ii) is consistent with the objectives of the SEC Pay-to-Play Rule.

[23] *See* Notice, 80 FR at 81651, 81656.

[24] *See id.* at 81651, 81655–56.

[25] *See id.* at 81655 n.60 (citing Advisers Act Rule 204–2(a)(18) and (h)(1)).

The following is an overview of some of the key terms used in FINRA's proposed Rule 2030, as discussed by FINRA in its filing and published in the Notice or as defined in proposed Rule 2030(g).

1. Covered Members

The SEC Pay-to-Play Rule includes within its definition of "regulated person" SEC-registered municipal advisors, subject to specified conditions.[29] Specifically, the SEC Pay-to-Play Rule prohibits an investment adviser from providing or agreeing to provide, directly or indirectly, payment to an SEC-registered municipal advisor unless the municipal advisor is subject to a Municipal Securities Rulemaking Board ("MSRB") pay-to-play rule.[30]

FINRA addresses the interplay between its proposed rule and the application of the MSRB's municipal advisor pay-to-play rule by exempting from the definition of "covered member" a member when it is "engaging in activities that would cause the member to be a municipal advisor as defined in Exchange Act Section 15B(e)(4), SEA Rule 15Ba1–1(d)(1) through (4) and other rules and regulations thereunder." [31] FINRA states that a member firm that solicits a government entity for investment advisory services on behalf of an *unaffiliated* investment adviser may be required to register with the SEC as a municipal advisor as a result of such activity.[32] Under such circumstances, FINRA notes that the MSRB rules applicable to municipal advisors, including the pay-to-play rule adopted by the MSRB,[33] would apply to the member firm.[34] On the other hand, if the member firm solicits a government entity on behalf of an *affiliated* investment adviser, such activity would not cause the firm to be a municipal advisor.[35] Under such circumstances, the member firm would be a "covered member" subject to the requirements of proposed Rule 2030.[36] This distinction is the result of the definitions of "municipal advisor" and "solicitation of a municipal entity or obligated person" in the Exchange Act, which only covers a person who is not affiliated with the broker, dealer, municipal securities dealer, municipal advisor, or investment adviser for whom the person is soliciting.[37]

2. Distribution Activities

With respect to the triggering activities for FINRA's proposed Rule 2030(a), FINRA states that, based on the definition of "regulated person" in the SEC Pay-to-Play Rule,[38] it is proposing a rule that prohibits its member firms from engaging in distribution activities (as well as solicitation activities) for compensation with government entities for two years after certain political contributions have been made to certain officials.[39] FINRA also notes, in response to certain comments discussed below, that certain language in the SEC Pay-to-Play Rule Adopting Release further supports the inclusion of distribution activities by broker-dealers in FINRA's proposed Rule 2030.[40]

FINRA explains that the proposed rule would not apply to distribution activities related to registered investment companies that are not investment options of a government entity's plan or program because in these circumstances a member firm is not providing or seeking to provide investment advisory services to a government entity.[41] Therefore, the proposed rule would apply to distribution activities involving unregistered pooled investment vehicles such as hedge funds, private equity funds, venture capital funds, collective investment trusts, and registered pooled investment vehicles such as mutual funds, but only if those registered pools are an investment option of a participant-directed plan or program of a government entity.[42] FINRA also notes that, consistent with the SEC Pay-to-Play Rule, to the extent mutual fund distribution fees are paid by the fund using fund assets pursuant to a 12b-1 plan, such payments generally would not constitute payments by the fund's investment adviser.[43] However, if the adviser pays for the fund's distribution out of its "legitimate profits," the proposed rule would generally be implicated.[44]

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[26] *See* Notice, 80 FR at 81651.

[27] *See id.* at 81651. *See also id.* at 81651 n.19 (citing 17 CFR 275.206(4)–5(a)(1)).

[28] *Notice,* 80 FR at 81651, 81659.

[29] *See* 17 CFR 275.206(4)–5(a)(2)(i)(A) and 17 CFR 275.206(4)–5(f)(9).

[30] *See supra* note 29.

[31] Proposed Rule 2030(g)(4). *See also* Notice, 80 FR at 81652 (explaining that the SEC Pay-to-Play Rule includes within its definition of "regulated person" SEC-registered municipal advisors, subject to specified conditions, and prohibits an investment adviser from providing or agreeing to provide, directly or indirectly, payment to an SEC-registered municipal advisor unless the municipal advisor is subject to a MSRB pay-to-play rule).

[32] *See* Notice, 80 FR at 81652.

[33] On February 17, 2016, the MSRB published a regulatory notice announcing that its pay-to-play rule was deemed approved pursuant to section 19(b)(2)(D) of the Exchange Act on February 13, 2016 and that the effective date of the rule is August 17, 2016. *See* Amendments to MSRB Rule G–37 on Political Contributions and Prohibitions on Municipal Securities Business and Related Amendments are Deemed Approved under the Securities Exchange Act of 1934, Regulatory Notice 2016–06, dated February 17, 2016 (the "MSRB Regulatory Notice"), available at *http://www.msrb.org/~/media/Files/Regulatory-Notices/Announcements/2016-06.ashx?n=1.*

[34] *See* Notice, 80 FR at 81652.

[35] *See id.*

[36] *See id.* FINRA also notes that a person that is registered under the Exchange Act as a broker-dealer and municipal advisor, and under the Advisers Act as an investment adviser could potentially be a "regulated person" for purposes of the SEC Pay-to-Play Rule and that such a regulated person would be subject to the rules that apply to the services the regulated person is performing. *See id.* at n.24.

[37] Exchange Act Section 15B(e)(4) provides that a "municipal advisor" includes a person that undertakes solicitation of a municipal entity or obligated person. 15 U.S.C. 78o–4(e)(4). Exchange Act Section 15B(e)(9) provides that the term "solicitation of a municipal entity or obligated person" means "a direct or indirect communication with a municipal entity or obligated person made by a person, for direct or indirect compensation, on behalf of a broker, dealer, municipal securities dealer, municipal advisor, or investment adviser (as defined in section 202 of the Investment Advisers Act of 1940) that does not control, is not controlled by, or is not under common control with the person undertaking such solicitation for the purpose of obtaining or retaining an engagement by a municipal entity or obligated person of a broker, dealer, municipal securities dealer, or municipal advisor for or in connection with municipal financial products, the issuance of municipal securities, or of an investment adviser to provide investment advisory services to or on behalf of a municipal entity." 15 U.S.C. 78o–4(e)(9).

[38] A "regulated person," as defined in the SEC Pay-to-Play Rule, includes a FINRA member firm, provided that: (a) FINRA rules "prohibit member firms from engaging in distribution or solicitation activities if certain political contributions have been made;" and (b) "[t]he Commission finds, by order, that such rules impose substantially equivalent or more stringent restrictions on broker-dealers than [the SEC Pay-to-Play Rule] imposes on investment advisers and that such rules are consistent with the objectives of [the SEC Pay-to-Play Rule]." 17 CFR 275.206(4)–5(f)(9)(ii).

[39] *See* Notice, 80 FR at 81660–61 (explaining that FINRA believes its proposed rule must apply to member firms engaging in distribution activities and that FINRA did not revise the proposed rule to remove references to the term "distribution" as requested by comments received in response to *Regulatory Notice* 14–50).

[40] *See* Notice, 80 FR at 81660. *See also id.* at 81661 n.103 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 n.298 where, according to FINRA, the Commission "clarif[ied] under what circumstances distribution payments would violate the SEC's Pay-to-Play Rule").

[41] *See* Notice, 80 FR at 81661 n.106 (explaining that, although the proposed rule would not apply to distribution activities relating to all registered pooled investment vehicles, pursuant to proposed Rule 2030(e) "[i]t shall be a violation of this Rule for any covered member or any of its covered associates to do anything indirectly that, if done directly, would result in a violation of this Rule").

[42] *See id.* at 81661. *See also id.* at 81651 n.17 and 81654 n.46.

3. Solicitation Activities

FINRA states that, consistent with the SEC Pay-to-Play Rule, proposed Rule 2030(g)(11) defines the term "solicit" to mean:

> (A) With respect to investment advisory services, to communicate, directly or indirectly, for the purpose of obtaining or retaining a client for, or referring a client to, an investment adviser; and (B) With respect to a contribution or payment, to communicate, directly or indirectly, for the purpose of obtaining or arranging a contribution or payment.[45]

FINRA notes that, although the determination of whether a particular communication would be a solicitation would depend on the facts and circumstances relating to such communication, as a general proposition FINRA believes that any communication made under circumstances reasonably calculated to obtain or retain an advisory client would be considered a solicitation unless the circumstances otherwise indicate that the communication does not have the purpose of obtaining or retaining an advisory client.[46]

4. Investment Advisers

Proposed Rule 2030 would apply to covered members acting on behalf of (as defined in proposed Rule 2030(g)(7)) any investment adviser registered (or required to be registered) with the Commission, or unregistered in reliance on the exemption available under Section 203(b)(3) of the Advisers Act for foreign private advisers, or that is an exempt reporting adviser under Advisers Act Rule 204–4(a).[47] Thus, proposed Rule 2030 would not apply to member firms acting on behalf of advisers that are registered with state securities authorities instead of the SEC, or advisers that are unregistered in reliance on exemptions other than Section 203(b)(3) of the Advisers Act or Advisers Act Rule 204–4(a). The proposed rule's definition of "investment adviser" is consistent with the definition of "investment adviser" in the SEC Pay-to-Play Rule.[48]

5. Official of a Government Entity

FINRA explains that an "official" (as defined in proposed Rule 2030(g)(8)) of a "government entity" (as defined in proposed Rule 2030(g)(7))—both of which FINRA states are consistent with the SEC Pay-to-Play Rule definitions—would include an incumbent, candidate or successful candidate for elective office of a government entity if the office is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser or has authority to appoint any person who is directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser.[49] FINRA also notes that it is the scope of authority of the particular office of an official, not the influence actually exercised by the individual, that would determine whether the individual has influence over the awarding of an investment advisory contract under the definition.[50] FINRA also explains that government entities would include all state and local governments, their agencies and instrumentalities, and all public pension plans and other collective government funds, including participant-directed plans such as 403(b), 457, and 529 plans.[51]

6. Contributions

Proposed Rule 2030(g)(1) defines "contribution" to mean any gift, subscription, loan, advance, deposit of money, or anything of value made for the purpose of influencing the election for a federal, state or local office, and includes any payments for debts incurred in such an election or transition or inaugural expenses incurred by a successful candidate for state or local office.[52] FINRA states that this definition is consistent with the SEC Pay-to-Play Rule.[53] FINRA also states that it would not consider a donation of time by an individual to be a contribution, provided the covered member has not solicited the individual's efforts and the covered member's resources, such as office space and telephones, are not used.[54] FINRA further states that it would not consider a charitable donation made by a covered member to an organization that qualifies for an exemption from federal taxation under the Internal Revenue Code, or its equivalent in a foreign jurisdiction, at the request of an official of a government entity to be a contribution for purposes of the proposed rule.[55]

7. Covered Associates

Proposed Rule 2030(g)(2) defines the term "covered associates" to mean:

> (A) Any general partner, managing member or executive officer of a covered member, or other individual with a similar status or function; (B) Any associated person of a covered member who engages in distribution or solicitation activities with a government entity for such covered member; (C) Any associated person of a covered member who supervises, directly or indirectly, the government entity distribution or solicitation activities of a person in subparagraph (B) above; and (D) Any political action committee controlled by a covered member or a covered associate.[56]

FINRA states that, as also noted in the SEC Pay-to-Play Rule Adopting Release, contributions made to influence the selection process are typically made not by the firm itself, but by officers and employees of the firm who have a direct economic stake in the business relationship with the government client.[57] For example, contributions by an "executive officer of a covered member" (as defined in proposed Rule 2030(g)(5)) would trigger the two-year "time-out."[58] FINRA also notes that whether a person is an executive officer would depend on his or her function or activities and not his or her title.[59] In addition, FINRA states that a covered associate would include a PAC controlled by the covered member or any of its covered associates.[60] FINRA explains that it would consider a "covered member" (as defined in proposed Rule 2030(g)(4)) or its covered associates to have "control" over a PAC if the covered member or covered associate has the ability to direct or cause the direction of governance or operations of the PAC.[61]

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[43] *See id.* at 81661 n.103. *See also* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 n.298 (discussing how broker-dealers may be compensated by advisers according to distribution arrangements and noting that "[m]utual fund distribution fees are typically paid by the fund pursuant to a 12b-1 plan, and therefore generally would not constitute payment by the fund's adviser. As a result, such payments would not be prohibited [under the SEC Pay-to-Play Rule] by its terms").

[44] *See* Notice, 80 FR at 81661 n.103 (noting, among other things, that "for private funds, third parties are often compensated by the investment adviser or its affiliated general partner"). For a discussion of a mutual fund adviser's ability to use "legitimate profits" for fund distribution, *see* Investment Company Act of 1940 Release No. 11414 (Oct. 28, 1980), 45 FR 73898 (Nov. 7, 1980) (Bearing of Distribution Expenses by Mutual Funds).

[45] Notice, 80 FR at 81651 n.18. *See also id.* at 81653–54 n.40.

[46] *See id.* at 81651 n.18. *See also id.* at 81653–54 n.40.

[47] *See* Proposed Rule 2030(g)(7).

[48] *See* 17 CFR 275.206(4)–5(a)(1).

[49] *See* Notice, 80 FR at 81652.

[50] *See id.* (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41029 (discussing the terms "official" and "government entity").

[51] *See* Notice, 80 FR at 81652.

[52] *See id.* at 81652.

[53] *See id.* at 81652 n.32. *See also id.* at 81653.

[54] *See id.* at 81653 n.33 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41030).

[55] *See* Notice, 80 FR at 81653.

[56] *Id.* at 81653 n.37.

[57] *See id.* (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41031).

[58] *See* Notice, 80 FR at 81653.

[59] *See id.*

[60] *See id.*

B. Proposed Rule 2030(b): Prohibition on Soliciting and Coordinating Contributions

Proposed Rule 2030(b) also would prohibit a covered member or covered associate from soliciting or coordinating any person or political action committee ("PAC") to make any: (1) Contribution to an official of a government entity in respect of which the covered member is engaging in, or seeking to engage in, distribution or solicitation activities on behalf of an investment adviser; or (2) payment to a political party of a state or locality of a government entity with which the covered member is engaging in, or seeking to engage in, distribution or solicitation activities on behalf of an investment adviser.[62] FINRA states that this provision is modeled on a similar provision in the SEC Pay-to-Play Rule[63] and is intended to prevent covered members or covered associates from circumventing the proposed rule's two-year "time-out" by "bundling," either by soliciting a large number of contributions by employees, or by soliciting payments to a State or local political party.[64]

C. Proposed Rule 2030(c): Exceptions

FINRA's proposed pay-to-play rule contains three exceptions from the proposed rule's prohibitions: (1) *de minimis* contributions; (2) new covered associates; and (3) certain returned contributions.[65] FINRA states that these exceptions are modeled on similar exceptions in the SEC Pay-to-Play Rule.[66]

1. De Minimis Contribution Exception

Proposed Rule 2030(c)(1) would except from the rule's restrictions contributions made by a covered associate who is a natural person to government entity officials for whom the covered associate was entitled to vote at the time of the contributions, provided the contributions do not exceed $350 in the aggregate to any one official per election.[67] If the covered associate was not entitled to vote for the official at the time of the contribution, the contribution must not exceed $150 in the aggregate per election.[68] FINRA states that, consistent with the SEC Pay-to-Play Rule, under this exception, primary and general elections would be considered separate elections.[69] FINRA also explains that this exception is based on the theory that such contributions are typically made without the intent or ability to influence the selection process of the investment adviser.[70]

2. Exception for Certain New Covered Associates

The proposed rule would attribute to a covered member contributions made by a person within two years (or, in some cases, six months) of becoming a covered associate. However, proposed Rule 2030(c)(2) would provide an exception from the proposed rule's restrictions for covered members if a natural person made a contribution more than six months prior to becoming a covered associate of the covered member unless the covered associate engages in, or seeks to engage in, distribution or solicitation activities with a government entity on behalf of the covered member.[71] FINRA states that this exception is consistent with the SEC Pay-to-Play Rule[72] and is intended to balance the need for covered members to be able to make hiring decisions against the need to protect against individuals marketing to prospective employers their connections to, or influence over, government entities the employer might be seeking as clients.[73] FINRA also provides, with respect to the "look back" provisions in the proposed rules generally, the following illustrations of how the "look back" provisions will work: If, for example, the contributions were made more than two years (or six months for new covered associates) prior to the employee becoming a covered associate, the "time-out" has run.[74] According to FINRA, however, if the contribution was made less than two years (or six months, as applicable) from the time the person becomes a covered associate, the proposed rule would prohibit the covered member that hires or promotes the contributing covered associate from receiving compensation for engaging in distribution or solicitation activities on behalf of an investment adviser from the hiring or promotion date until the applicable period has run.[75]

3. Exception for Certain Returned Contributions

Proposed Rule 2030(c)(3) would provide an exception from the proposed rule's restrictions for covered members if the restriction is due to a contribution made by a covered associate and: (1) The covered member discovered the contribution within four months of it being made; (2) the contribution was less than $350; and (3) the contribution is returned within 60 days of the discovery of the contribution by the covered member.[76] FINRA explains that, consistent with the SEC Pay-to-Play Rule, this exception would allow a covered member to cure the consequences of an inadvertent political contribution.[77] The proposed rule also would provide that covered members with 150 or fewer registered representatives would be able to rely on this exception no more than two times per calendar year, while covered members with more than 150 registered representatives would be permitted to rely on this exception no more than three times per calendar year.[78] Furthermore, a covered member would not be able to rely on an exception more than once with respect to contributions by the same covered associate regardless of the time period, which is consistent with similar provisions in the SEC Pay-to-Play Rule.[79]

D. Proposed Rule 2030(d): Prohibitions as Applied to Covered Investment Pools

Proposed Rule 2030(d)(1) provides that a covered member that engages in distribution or solicitation activities with a government entity on behalf of a covered investment pool,[80] in which a government entity invests or is solicited to invest, shall be treated as though the covered member was engaging in or seeking to engage in distribution or solicitation activities with the government entity on behalf of the investment adviser to the covered investment pool directly.[81] Proposed Rule 2030(d)(2) provides that an investment adviser to a covered investment pool in which a government entity invests or is solicited to invest shall be treated as though that investment adviser were providing or seeking to provide investment advisory services directly to the government entity.[82] FINRA states that proposed Rule 2030(d) is modeled on a similar prohibition in the SEC Pay-to-Play Rule and would apply the prohibitions of the proposed rule to situations in which an investment adviser manages assets of a government entity through a hedge fund or other type of pooled investment vehicle.[83] Therefore, according to FINRA, the provision would extend the protection of the proposed rule to public pension plans that access the services of investment advisers through hedge funds and other types of pooled investment vehicles sponsored or advised by investment advisers as a funding vehicle or investment option in a government-sponsored plan, such as a 529 plan.[84]

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[61] *See id.*

[62] *See id.* at 81653–54. *See also id.* at 81662.

[63] *See id.* at 81654 n.42 (citing 17 CFR 275.206(4)–5(a)(2)).

[64] *See* Notice, 80 FR at 81654.

[65] *See id.*

[66] *See id.* at n.51 (citing 17 CFR 275.206(4)–5(b)).

[67] *See* Notice, 80 FR at 81655.

[68] *See id.*

[69] *See id.* at 81655 n.54 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41034).

[70] *See* Notice, 80 FR at 81655.

[71] *See id.*

[72] *See id.* at 81655 n.55 (citing 17 CFR 275.206(4)–5(b)(2)).

[73] *See* Notice, 80 FR at 81655.

[74] *See id.* at 81656.

[75] *See id.* at 81655–56.

[76] *See id.* at 81655.

[77] *See id.*

[78] *See id.* FINRA notes that these limitations are consistent with similar provisions in the SEC Pay-to-Play Rule 206(4)–5(b)(3), although the SEC Pay-to-Play Rule includes different allowances for larger and smaller investment advisers based on the number of employees they report on Form ADV. *See id.* at 81655 n.59.

[79] *See* Notice, 80 FR at 81655.

[80] *See id.* at 81654 n.46 (proposed Rule 2030(g)(3) defines a "covered investment pool" to mean: "(A) Any investment company registered under the Investment Company Act that is an investment option of a plan or program of a government entity; or (B) Any company that would be an investment company under Section 3(a) of the Investment Company Act but for the exclusion provided from that definition by either Section 3(c)(1), 3(c)(7) or 3(c)(11) of that Act").

As noted above, the proposed rule would not apply to distribution activities related to registered investment companies that are not investment options of a government entity's plan or program because in these circumstances a member firm is not providing or seeking to provide investment advisory services to a government entity.[85] The proposed rule would apply to distribution activities involving unregistered pooled investment vehicles such as hedge funds, private equity funds, venture capital funds, collective investment trusts, and registered pooled investment vehicles such as mutual funds, but only if those registered pools are an investment option of a participant-directed plan or program of a government entity.[86]

E. Proposed Rule 2030(e): Prohibition on Indirect Contributions or Solicitations

Proposed Rule 2030(e) provides that it shall be a violation of Rule 2030 for any covered member or any of its covered associates to do anything indirectly that, if done directly, would result in a violation of the rule.[87] FINRA states that this provision is consistent with a similar provision in the SEC Pay-to-Play Rule [88] and would prevent a covered member or its covered associates from funneling payments through third parties, including, for example, consultants, attorneys, family members, friends, or companies affiliated with the covered member as a means to circumvent the proposed rule.[89] FINRA also notes that, consistent with guidance provided by the Commission in connection with SEC Pay-to-Play Rule 206(4)–5(d), proposed Rule 2030(e) requires a showing of intent to circumvent the rule for such persons to trigger the two-year "time-out." [90]

F. Proposed Rule 2030(f): Exemptions

Proposed Rule 2030(f) includes an exemptive provision for covered members, modeled on the exemptive provision in the SEC Pay-to-Play Rule, that would allow covered members to apply to FINRA for an exemption from the proposed rule's two-year "time-out." [91] As proposed, FINRA states that this provision would allow FINRA to exempt covered members, either conditionally or unconditionally, from the proposed rule's time-out requirement where the covered member discovers contributions that would trigger the compensation ban after they have been made, and when imposition of the prohibition would be unnecessary to achieve the rule's intended purpose.[92] In determining whether to grant an exemption, FINRA would take into account varying facts and circumstances, outlined in the proposed rule, that each application presents [93] (*e.g.,* the timing and amount of the contribution, the nature of the election, and the contributor's apparent intent or motive in making the contribution).[94] FINRA notes that this provision would provide covered members with an additional avenue by which to seek to cure the consequences of an inadvertent violation by the covered member or its covered associates that falls outside the limits of one of the proposed rule's exceptions.[95]

G. Proposed Rule 4580: Recordkeeping Requirements

Proposed Rule 4580 would require covered members that engage in distribution or solicitation activities with a government entity on behalf of any investment adviser that provides or is seeking to provide investment advisory services to such government entity to maintain books and records that would allow FINRA to examine for compliance with its pay-to-play rule.[96] FINRA states that this provision is consistent with similar recordkeeping requirements imposed on investment advisers in connection with the SEC Pay-to-Play Rule.[97] The proposed rule also would require covered members to maintain a list or other record of certain specific information.[98] FINRA states that the proposed rule would require, among other things, that the direct and indirect contributions or payments made by the covered member or any of its covered associates be listed in chronological order and indicate the name and title of each contributor and each recipient of the contribution or payment, as well as the amount and date of each contribution or payment, and whether the contribution was the subject of the exception for returned contributions in proposed Rule 2030.[99]

III. Summary of Comments and FINRA's Responses

In response to the Notice, the Commission received ten comment letters, from nine different commenters.[100] Six commenters generally express support for FINRA's proposal.[101] However, five of those commenters, while generally expressing support for the goals of the proposal, also raise certain concerns regarding various aspects of the proposal as drafted and recommended amendments to the proposal.[102] The other three commenters did not support the proposed rule as drafted based largely on concerns involving the First Amendment to the U.S. Constitution.[103] FINRA responded, stating that it considered the comments received by the Commission in response to the Notice, and that FINRA is not intending to make changes to the proposed rule text in response to the comments.[104]

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[81] *See* Notice, 80 FR at 81654 n.47 (FINRA notes that, consistent with the SEC Pay-to-Play Rule, under the proposed rule, if a government entity is an investor in a covered investment pool at the time a contribution triggering a two-year time-out is made, the covered member must forgo any compensation related to the assets invested or committed by the government entity in the covered investment pool) (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41047).

[82] *See* Notice, 80 FR at 81654 n.48 (FINRA states that it added proposed Rule 2030(d)(2) in response to comments on *Regulatory Notice* 14–50 to clarify, for purposes of the proposed rule, the relationship between an investment adviser to a covered investment pool and a government entity that invests in the covered investment pool).

[83] *See* Notice, 80 FR at 81654 n.49 (citing 17 CFR 275.206(4)–5(c)).

[84] *See* Notice, 80 FR at 81654 n.50 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044, which discusses the applicability of the SEC Pay-to-Play Rule to covered investment pools).

[85] *See* Notice, 80 FR at 81661.

[86] *See id.*

[87] *See* Notice, 80 FR at 81654.

[88] *See id.* at n.44 (citing 17 CFR 275.206(4)–5(d)).

[89] *See* Notice, 80 FR at 81654 n.45 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044, which discusses direct and indirect contributions or solicitations).

[90] *See* Notice, 80 FR at 81654. *See also* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044 n.340 (explaining that like MSRB Rule G–37(d), SEC Pay-to-Play Rule 206(4)–5(d) "requires a showing of intent to circumvent the rule for such persons to trigger the time out") (citing *Blount*, 61 F.3d at 948 ("In short, according to the SEC, the rule restricts such gifts and contributions only when they are intended as end-runs around the direct contribution limitations.")).

[91] *See* Notice, 80 FR at 81654–55.

[92] *See id.* at 81655.

[93] *See id.*

[94] *See* Order Instituting Proceedings, 81 FR at 19263.

[95] *See* Notice, 80 FR at 81655.

[96] *See id.*

[97] *See id.* (citing 17 CFR 275.204–2(a)(18) and (h)(1)).

[98] *See* Notice, 80 FR at 81655–56.

[99] *See id.*

[100] *See supra* note 5. CAI submitted two separate comment letters in response to the Notice. *See* CAI Letter 1 and CAI Letter 2.

The Commission received an additional four comments in response to the Order Instituting Proceedings.[105] On July 6, 2016, FINRA submitted a letter responding to all comments and to the Order Instituting Proceedings.[106] The comments, as well as FINRA's responses, are summarized below.[107]

A. First Amendment Comments and FINRA's Responses

As noted above, five commenters either oppose the proposed rule[108] or raise certain issues regarding the proposed rule as drafted based largely on First Amendment concerns.[109] As a general matter, these commenters argue that FINRA's proposed rule is not narrowly tailored to serve a compelling government interest. While acknowledging that the D.C. Circuit upheld the constitutionality of a comparable MSRB pay-to-play rule in *Blount* v. *SEC,* 61 F.3d 938 (D.C. Cir. 1995), which also used analogous restrictions to discourage pay-to-play practices, these commenters believe that Supreme Court precedent has changed since *Blount* was decided.

In response to these comments, FINRA states that the points raised by the commenters do not warrant changes to, or disapproval of, its proposed rule change.[110] FINRA notes that the Commission has already reviewed and rejected these arguments in a nearly identical context.[111] As FINRA explains, the State Parties filed an unsuccessful lawsuit in 2014 challenging the SEC Pay-to-Play Rule on First Amendment grounds.[112] FINRA explains that the State Parties' comments opposing FINRA's proposed rule reiterate the arguments advanced in their suit against the Commission and, although the court of appeals decided the challenge on jurisdictional grounds, the brief that the Commission filed in the D.C. Circuit is persuasive in demonstrating that the State Parties' arguments lack merit.[113] FINRA also notes that the SEC Pay-to-Play Rule, upon which FINRA's proposed rule change is based, was modeled on pay-to-play rules that the MSRB drafted, that the Commission approved, and that the D.C. Circuit upheld against a constitutional challenge in *Blount.*[114]

Furthermore, FINRA states that the proposed rule change is justified by a sufficiently important governmental interest to withstand constitutional scrutiny. For example, FINRA explains that, as in *Blount,* the Commission's interest in preventing fraud and in protecting market actors from “unfair, corrupt market practices,” are “not only substantial, but . . . compelling.”[115] FINRA also notes that the Commission's interest in “clean advisory markets is equally important.”[116] FINRA acknowledges the D.C. Circuit's observation in *Blount* that “the link between eliminating pay-to-play practices and the Commission's goals of ‘perfecting the mechanism of a free and open market’ and promoting ‘just and equitable principles of trade’ is self-evident.”[117] In addition to noting the important interests served by its proposal, FINRA also notes that, as explained in *Blount,* the proposed rule change advances this government interest by seeking to halt an existing pay-to-play problem, even though, in terms of a record, “no smoking gun is needed;” however, “here, the conflict of interest is apparent, the likelihood of stealth great, and the [Commission's] purpose prophylactic.”[118]

FINRA further believes that the proposed rule change also is “closely drawn” to avoid unnecessary abridgment of associational freedoms.[119] FINRA explains that, like the pay-to-play rule upheld in *Blount,* its proposed rule change only “restricts a narrow range of . . . activities for a relatively short period of time,” and leaves available the “vast majority of political activities.”[120] For example, FINRA notes that the proposal does not attempt to regulate State and local elections, nor does it impose restrictions on independent expenditures or ban political contributions, and that each of those significant avenues for political expression remains unaffected by the proposed rule change.[121] FINRA also does not agree with arguments made by a commenter that FINRA did not consider less restrictive alternatives in drafting its proposal and that aspects of the proposal are vague or overbroad. FINRA notes that, because the Commission must find that FINRA's proposal imposes substantially equivalent or more stringent restrictions on its member firms as the SEC Pay-to-Play Rule imposes on investment advisers for FINRA members to be “regulated persons” under the SEC Pay-to-Play Rule, the provisions and definitions to which the commenter objects are modeled on and substantially similar to provisions in the

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[101] *See* CAI Letter 1; CAI Letter 2; FSI Letter 1; ICI Letter; NAIFA Letter; NASAA Letter; and PIABA Letter.

[102] *See* CAI Letter 1; CAI Letter 2; FSI Letter 1; NAIFA Letter; NASAA Letter; and PIABA Letter. ICI did not raise additional concerns, but states that it is satisfied with FINRA's revisions and responses to the proposal as drafted in *Regulatory Notice* 14–50. *See* ICI Letter.

[103] *See* CCP Letter 1; Moran Letter; and State Parties Letter 1. Other commenters also raise certain First Amendment-related concerns. *See* FSI Letter 1; and CAI Letter 1.

[104] *See* FINRA Response Letter 1.

[105] *See supra* note 10. *See* also Memorandum from the Division of Trading and Markets regarding a May 10, 2016 conference call with representatives of CAI; Memorandum from the Division of Trading and Markets regarding a May 19, 2016 conference call with representatives of FSI.

[106] *See supra* note 12.

[107] The comments received in response to the Notice were summarized when the Commission instituted proceedings. *See supra* note 9. For further detail, the comments that the Commission received on both the Notice and the Order Instituting Proceedings are available on the Commission's Web site at *http://www.sec.gov/comments/sr-finra-2015-056/finra2015056.shtml.*

[108] *See* CCP Letter 1; and State Parties Letter 1. *See also* CCP Letter 2; CCP Letter 3; and State Parties Letter 2.

[109] *See* CAI Letter 1; FSI Letter 1; FSI Letter 2; and Moran Letter.

[110] *See* FINRA Response Letter 2 at 3 (noting that FINRA's responses to the First Amendment arguments raised by the State Parties and CCP also address the concerns raised by CAI, FSI and Moran). A copy of FINRA Response Letter 2 is available at: *https://www.sec.gov/comments/sr-finra-2015-056/finra2015056-18.pdf.*

[111] *See id.* (citing *N.Y. Republican State Comm.* v. *SEC,* 799 F.3d 1126 (D.C. Cir. 2015) (affirming dismissal of the petition for lack of subject matter jurisdiction and also dismissing the petition as time-barred).

[112] *See* FINRA Response Letter 2 at 3.

[113] *See id.* at 3–4.

[114] *See id.* at 5 (citing *Blount,* 61 F.3d at 944).

[115] *See, e.g.,* FINRA Response Letter 2 at 5 (quoting *Blount,* 61 F.3d at 944).

[116] *See, e.g.,* FINRA Response Letter 2 at 5 (quoting an observation made in *Blount* that the Commission's interest “in clean bond markets” is just as important as a legislature's interest “in clean elections”) (quoting *Blount,* 61 F.3d at 944)).

[117] *See, e.g.,* FINRA Response Letter 2 at 5 (quoting *Blount,* 61 F.3d at 945).

[118] *See, e.g.,* FINRA Response Letter 2 at 6 (quoting *Blount,* 61 F.3d at 945).

[119] *See, e.g.,* FINRA Response Letter 2 at 6.

[120] *See, e.g., id.* (quoting *Blount,* 61 F.3d at 947–48).

[121] *See, e.g.,* FINRA Response Letter 2 at 4. *See also* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41024 n.71 (explaining that the SEC Pay-to-Play rule “imposes no restrictions on activities such as making independent expenditures to express support for candidates, volunteering, making speeches, and other conduct”).

SEC Pay-to-Play Rule.[122] FINRA also states that it will work with the industry and Commission to address interpretive questions and provide additional guidance, as needed, to the extent that questions arise regarding the application and scope of the provisions and terms used in the proposed rule change.[123]

B. Comments Regarding FINRA's Authority To Propose a Pay-to-Play Rule and FINRA's Responses

Several commenters contend that FINRA does not have the authority to adopt a pay-to-play rule because only Congress or the Federal Election Commission may regulate contributions for federal elections.

In response, FINRA states that the proposed rule change is consistent with the authority Congress granted a registered national securities association like FINRA under Section 15A(b)(6) of the Act to adopt rules that are designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.[124] FINRA believes that the proposed rule change accomplishes the goals of Section 15A(b)(6) by, for example, allowing member firms to continue to engage in distribution or solicitation activities for compensation with governmental entities on behalf of investment advisers, while at the same time deterring member firms from engaging in pay-to-play practices.[125] FINRA also believes that the proposed rule change is reasonably designed to address the distortion of the investment advisory market and collective action problems created by pay-to-play practices.[126]

Although FINRA acknowledges that the proposed rule's two-year "time-out" provision might result in fewer covered members and their covered associates making certain political contributions to certain officials, FINRA notes that if it did not adopt a pay-to-play rule, the SEC Pay-to-Play Rule would prohibit member firms from soliciting government entities for investment advisory services for compensation on behalf of investment advisers.[127] FINRA explains that the SEC Pay-to-Play Rule provides that the rules of a self-regulatory organization ("SRO"), like FINRA, must impose "substantially equivalent or more stringent restrictions" on its member firms that wish to act as "regulated persons" as the SEC Pay-to-Play Rule imposes on investment advisers.[128] Therefore, unless FINRA imposes sufficiently stringent restrictions, investment advisers and covered associates will be barred from providing or agreeing to provide, directly or indirectly, payment to FINRA member firms to solicit a government entity for investment advisory services on behalf of the investment adviser.[129] FINRA believes that the proposed rule change is a more effective response to the issues addressed in the SEC Pay-to-Play Rule than a complete ban on solicitation,[130] and notes throughout its response that the proposal imposes substantially equivalent restrictions on FINRA member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[131]

C. Variable Annuity-Related Comments and FINRA's Responses

Two commenters raise concerns regarding the application of the proposed rules to variable annuities.[132] Both of these commenters request, as a threshold matter, that FINRA confirm that Rule 2030 would not apply to variable annuities.[133] One of these commenters requests that the proposed rule not apply to the sales of variable annuity contracts supported by a separate account that invests in mutual funds, arguing that the nature of variable annuities and the way investment options are selected does not implicate the investment advisory solicitation activities contemplated by the SEC Pay-to-Play Rule.[134] This commenter claims that the relationship between a variable annuity contract holder and the investment adviser to a mutual fund supporting the variable annuity does not rise to a level such that it should implicate the proposed pay-to-play rule's restrictions.[135] The other commenter claims, in support of its argument that Rule 2030 should not apply to variable annuities, that compliance with Rule 2030 would be impractical for broker-dealers selling variable annuities in the government market.[136] This commenter also argues, for example, that a covered member selling a variable annuity, particularly where the separate account is registered as a unit investment trust, cannot fairly be seen to be engaging in solicitation activities on behalf of all of the investment advisers and sub-advisers that manage the covered investment pools available as investment options under the separate account and subaccounts.[137]

This commenter also requests that proposed Rule 2030 be modified to, among other things, clarify that the distribution of a two-tiered product such as a variable annuity is not solicitation activity for an investment adviser and sub-advisers managing the funds available as investment options.[138] Furthermore, this same commenter states that if FINRA or the Commission determines that broker-dealers selling variable annuities constitute solicitation activities for purposes of Rule 2030, that determination raises a host of interpretive questions that, in this commenter's view, would require further guidance from FINRA or the Commission.[139]

In response, FINRA states that its proposed rules must impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[140] Therefore, because the Commission did not exclude specific products from the SEC Pay-to-Play Rule, such as variable annuities, FINRA does not believe that excluding specific products from its proposed rule would satisfy the Commission's stringency requirements.[141] FINRA notes, however, that to the extent interpretive questions arise regarding the application and scope of the provisions and terms used in its proposed rules, FINRA will work with the industry and Commission to address those interpretive questions and provide additional guidance as needed.[142]

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[122] *See, e.g.,* FINRA Response Letter 2 at 7.

[123] *See, e.g., id.*

[124] *See id.*

[125] *See id.*

[126] *See id.* at 9. As outlined in the SEC Pay-to-Play Adopting Release, pay-to-play activities create a "collective action" problem in two respects. First, government officials who participate in such activities may have an incentive to continue to accept contributions to support their campaigns for fear of being disadvantaged relative to their opponents. Second, advisers may have an incentive to participate out of concern that they may be overlooked if they fail to make a contribution. *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 40122.

[127] *See* FINRA Response Letter 2 at 4–5.

[128] *See id.* at 4.

[129] *See id. See also* Notice, 80 FR at 81659.

[130] *See* FINRA Response Letter 2 at 4.

[131] *See, e.g., id.* at 4, 7.

[132] *See* CAI Letter 1 and FSI Letter 1. *See also* CAI Letter 2 (reflecting CAI's suggested revisions to the certain language in some of FINRA's proposed rules).

[133] *See* CAI Letter 1 and FSI Letter 1.

[134] *See* FSI Letter 1 (claiming that applying the proposed rule to variable annuities will significantly increase the compliance burden and as such may limit the options their members make available to 403(b) and 457 plans).

[135] *See* FSI Letter 1.

[136] *See* CAI Letter 1 (claiming that the dynamics and structure of variable annuities, particularly those with separate accounts registered as a unit investment trust, and the number of advisers and sub-advisers to the funds underlying sub-accounts, makes compliance with proposed Rule 2030 impractical).

[137] *See id.*

[138] *See id.*

[139] *See id.* For example, CAI requests guidance on the following questions: Is the selling broker-dealer deemed to be soliciting on behalf of the adviser of each of the underlying funds or only of advisers and sub-advisers of funds underlying investment options that are selected by contract holders? If an underlying fund is managed by an adviser that uses multiple sub-advisers, is the selling firm deemed to be soliciting on behalf of all of the sub-advisers? How does the rule apply when a contract holder on his or her own allocates funds in the variable annuity to an option at a point of time (for example, five years) subsequent to the purchase of the variable annuity without any involvement of the selling firm? *See id.*

D. Comments Regarding the Scope of the Proposed Rule and FINRA's Responses

Two commenters also express concern that proposed Rule 2030(d) would, in their view, re-characterize "ordinary" or "customary" distribution activities for covered investment pools as the solicitation of clients on behalf of the investment adviser to the covered investment pools.[143] One of these commenters requests that such customary distribution activity by member firms for covered investment pools sold to government entities *not* be treated as solicitation activity for an investment adviser for purposes of Rule 2030 simply because an investment adviser provides advisory services to a covered investment pool that is available as an investment option.[144] As more fully explained in the commenter's letter, the commenter claims, for example, that proposed Rule 2030(d) would recast "traditional" broker-dealer activity (*i.e.*, the offer and sale of covered investment pool securities pursuant to a selling or placement agent agreement) into something it is not: The solicitation of investment advisory services on behalf of an investment adviser.[145] This commenter also claims that the decision in *Goldstein* v. *SEC*, 451 F.3d 873 (D.C. Cir. 2006) and the Commission staff's interpretive position under Advisers Act Rule 206(4)–3 suggest that proposed Rule 2030(d) would be impractical.[146] This commenter also notes that Rule 206(4)–3 puts selling firms in a contradictory position under FINRA rules and Advisers Act rules.[147] This commenter further states that, in its view, a broker-dealer that offers and sells interests in a mutual fund or private fund cannot be characterized as soliciting on behalf of the investment adviser to a covered investment pool.[148]

Similarly, another commenter expresses concern with the apparent application of proposed Rule 2030(d) to "traditional" brokerage sales of mutual funds and variable annuities to participant-directed government-sponsored retirement plans.[149] As more fully explained in the commenter's letter, this commenter continues to be concerned that the provisions in proposed Rule 2030(d) go beyond that which is required under Rule 206(4)–5(a)(2)(i) and Rule 206(4)–5(c) to the detriment of investors.[150] This same commenter also claims that mutual fund sales, as well as variable annuity sales, should be excluded, claiming that the proposed rules serve to redefine the sale of mutual funds as solicitation by a broker-dealer on behalf of an investment adviser and also conflict with the realities of conventional mutual fund selling agreements.[151]

In response, FINRA explains that, in proposing FINRA Rule 2030(d), it did not intend to re-characterize broker-dealers' selling interests in variable annuities, mutual funds and private funds as soliciting an investment advisory relationship with investors who invest in those products.[152] Rather, FINRA states that the purpose of proposed Rule 2030(d) is to clarify that the prohibition of proposed Rule 2030(a) would apply when the covered member is engaging in distribution or solicitation activities with a government entity on behalf of a covered investment pool.[153] FINRA further explains that proposed Rule 2030(d) is modeled on a similar provision in the SEC Pay-to-Play Rule, Rule 206(4)–5(c).[154] As such, and consistent with SEC Pay-to-Play Rule 206(4)–5(c), proposed Rule 2030(d) is intended to extend the protections of the proposed rule to government entities that access the services of investment advisers through hedge funds and other types of pooled investment vehicles sponsored or advised by investment advisers.[155] Finally, FINRA notes that the applicability of proposed Rule 2030(d) is for purposes of FINRA's pay-to-play rule only and, as such, would not impact or otherwise affect other FINRA rules or guidance. Therefore, FINRA has determined not to make the changes suggested by the commenters.[156]

E. Comments Regarding the Inclusion of Distribution Activity in the Proposed Rule and FINRA's Responses

One commenter generally expresses concern that proposed Rule 2030 is unnecessarily ambiguous regarding the term "distribution" activities in Rule 2030(a).[157] This commenter claims that it is unclear what distribution activities "with" a government entity would be prohibited, what compensation is covered by the proposed rule and who must pay it, and when a member firm might be deemed to be acting "on behalf of" an investment adviser.[158] This commenter states that the ambiguity of proposed Rule 2030 may result in its misapplication in a variety of contexts, such as: Where a selling firm is affiliated with one, but not all, underlying fund advisers and none of the sub-adviser(s) to any underlying funds, or none of the underlying fund advisers, but some of the sub-advisers.[159]

This commenter also claims that, while the SEC Pay-to-Play Rule requires regulated persons to be subject to rules that prohibit them from engaging in certain distribution activities if certain political contributions have been made, SEC Pay-to-Play Rule 206(4)–5 does not mandate the use of the term "distribution" in describing the conduct prohibited by the proposed rule, and suggested revised rule text reflecting that assertion.[160] The commenter believes that its suggested revisions would eliminate, among other things, the potential concern that a selling firm might violate proposed Rule 2030 unknowingly due to being deemed to be acting on behalf of investment advisers or sub-advisers of underlying funds with which it has no relationship.[161]

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[140] *See* FINRA Response Letter 2 at 16.

[141] *See id.*

[142] *See id.*

[143] *See* CAI Letter 1 and FSI Letter 1.

[144] *See* CAI Letter 1.

[145] *See id.*

[146] *See id.* (claiming that "[i]t would create significant confusion in the industry and undermine settled practices and understandings, while creating doubt as to the application of the *Goldstein* case and the Commission staff's guidance in the Mayer Brown no-action letter").

[147] *See id.*

[148] *See id.*

[149] *See* FSI Letter 1. *See also* FSI Letter 2

[150] *See* FSI Letter 1. *See also* FSI Letter 2.

[151] *See* FSI Letter 1. *See also* FSI Letter 2.

[152] *See* FINRA Response Letter 2 at 14.

[153] *See id.*

[154] *See id.*

[155] *See id.* at 15 (noting that when adopting SEC Pay-to-Play Rule 206(4)–5(c), the Commission stated that although "an investment in a pooled investment vehicle may not involve a direct advisory relationship with a government sponsored plan [that] does not change the nature of the fraud or the harm that may be inflicted as a consequence of the adviser's pay-to-play activity") (quoting SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044–45)).

[156] *See* FINRA Response Letter 2 at 15.

[157] *See* CAI Letter 1.

[158] *See id.*

[159] *See id.*

[160] *See* CAI Letter 1 and CAI Letter 2 (reflecting CAI's suggested revisions to certain language in some of FINRA's proposed rules).

In response, FINRA states that it continues to maintain the position, outlined in the Notice, that it will not remove references to the term "distribution." [162] FINRA explains that the Notice pointed to language in the SEC Pay-to-Play Rule Adopting Release supporting the inclusion of distribution activities by broker-dealers in FINRA's proposed Rule 2030.[163] Specifically, FINRA pointed to the Commission's discussion regarding under what circumstances distribution payments would violate the SEC's Pay-to-Play Rule.[164] FINRA also notes that based on the Commission's definition of "regulated person" [165] in the SEC's Pay-to-Play Rule, as well as the Commission's discussion regarding the treatment of distribution fees paid pursuant to a 12b–1 plan as compared to legitimate profits, FINRA believes that its proposed rule must apply to member firms engaging in distribution activities.[166] FINRA mentioned previously, to the extent that interpretive questions arise regarding the application and scope of the provisions and terms used in the proposed rule change, FINRA will work with the industry and Commission to address the interpretive questions and provide additional guidance as needed.[167]

F. Comments Regarding Defined Terms Used in the Proposed Rules and FINRA's Responses

Two commenters request clarification of certain defined terms used in the proposed rules.[168] One commenter urged FINRA, or the Commission, to clarify the meaning of the term "instrumentality" as it is used in the definition of "government entity." [169] This commenter claims that, "[w]ithout additional guidance, covered members will continue to struggle with whether a contribution to a given entity should be treated as a contribution to an 'instrumentality' of a state or state agency, thus triggering the two-year time out. . . ." [170] This same commenter also asked for clarification as to whether each and every "contribution" (as defined in proposed Rule 2030(g)(1)) is, by definition, also a "payment" (as defined in proposed Rule 2030(g)(9)).[171]

Another commenter requests that FINRA clarify the definition of a "covered associate" and clarify and delineate the positions that would qualify someone as a covered "official." [172] This commenter claims that, in response to the same definition of "covered associate" as used in the SEC Pay-to-Play Rule, many investment advisers and broker-dealers have classified all of their representatives as covered associates regardless of whether they actually engage in the solicitation activity specified in the definition.[173] This commenter believes that additional clarification on when an associated person of a covered member would (or would not) qualify as a "covered associate" would ease compliance burdens, curtail overly broad limits on legitimate political activity, and increase the consistency of procedures amongst member firms who seek to comply with both the letter and the spirit of the proposed rule.[174] This same commenter requests additional details or guidance from the Commission with respect to this definition of "official" because, according to that commenter, that definition has caused, and will continue to spark confusion over exactly what offices subject the holder to be classified as an "official" given that the term is defined the same way in the SEC Pay-to-Play Rule.[175]

In response, FINRA states that it recognizes, as did the commenters, that these terms are defined in the SEC Pay-to-Play Rule and that FINRA modeled the definitions in its proposal on those in the SEC Pay-to-Play Rule.[176] With respect to CAI's request for clarification as to whether each and every "contribution" (as defined in proposed FINRA Rule 2030(g)(1)) is, by definition, also a "payment" (as defined in proposed FINRA Rule 2030(g)(9)), FINRA states that the definition of "payment" is similar to the definition of "contribution," but is broader because it does not include limitations on the purposes for which such money is given (*e.g.*, it does not have to be made for the purpose of influencing an election).[177] Finally, FINRA also acknowledges the concerns raised by the commenters and the requests for clarification and additional guidance from the Commission and FINRA as to certain terms.[178] FINRA again states that to the extent that interpretive questions arise regarding the application and scope of the provisions and terms used in the proposed rule change, FINRA will work with the industry and Commission to address the interpretive questions and provide additional guidance as needed.[179]

G. Comments Regarding PAC Contributions and FINRA's Responses

One commenter claims that statements made by FINRA in the Notice regarding the proposed rule's anti-circumvention provision, proposed Rule 2030(e), combined with statements made in Commission staff guidance concerning whether contributions through PACs would violate the SEC Pay-to-Play Rule and Section 208(d) of the Advisers Act, have the ability to chill contributions to PACs.[180] This commenter claims, for example, that prospective contributors who simply want to donate to a PAC have been hesitant to or restricted from doing so out of fear that they may be making an indirect contribution in violation of the SEC Pay-to-Play Rule.[181] Accordingly, this commenter requests further guidance from the Commission on the factors by which contributions to PACs would or would not trigger the anti-circumvention provision of the proposed rule.[182]

In response, FINRA again acknowledges the concerns raised by the commenter and the requests for clarification and additional guidance from the Commission and FINRA.[183] FINRA states that, to the extent that interpretive questions arise regarding the application and scope of the provisions and terms used in the proposed rule change, FINRA will work with the industry and Commission to address the interpretive questions and provide additional guidance as needed.[184]

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[161] *See* CAI Letter 1 (claiming that the commenter's suggested revisions would not result in any inappropriate narrowing of the scope of Rule 2030).

[162] *See* FINRA Response Letter 2 at 12.

[163] *See id.* at 11–12 (citing Notice, 80 FR at 81660–61).

[164] *See* FINRA Response Letter 2 at 12 n.52 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 4104 n.298).

[165] *See* FINRA Response Letter 2 at 12 (explaining that the SEC Pay-to-Play Rule defines a "regulated person" to include a member firm, provided that FINRA rules prohibit member firms from engaging in *distribution* or solicitation activities if political contributions have been made) (citing 17 CFR 275.206(4)–5(f)(9)(ii)(A)) (emphasis in original).

[166] *See* FINRA Response Letter 2 at 12 (citing Notice, 80 FR at 81660–61).

[167] *See id.*

[168] *See* CAI Letter 1 and NAIFA Letter.

[169] *See* CAI Letter 1 (claiming that CAI's members have struggled to understand the contours of this term in the context of the SEC Pay-to-Play Rule).

[170] *See id.*

[171] *See* CAI Letter 1 (discussing Notice, 80 FR at 81654 n.41: "Consistent with the SEC Pay-to-Play Rule, FINRA is including the broader term 'payments,' as opposed to 'contributions,' to deter a cover member from circumventing the proposed rule's prohibitions by coordinating indirect contributions to government officials by making payments to political parties").

[172] *See* NAIFA Letter.

[173] *See id.*

[174] *See id.*

[175] *See id.*

[176] *See* FINRA Response Letter 2 at 18.

[177] *See id.* at 17.

[178] *See id.* at 19.

[179] *See id.*

[180] *See* NAIFA Letter.

[181] *See id.*

[182] *See id.*

[183] *See* FINRA Response Letter 2 at 19.

Another commenter claims that it continues to believe that not all payments to political parties or PACs should have to be maintained under the books and records requirements of proposed Rule 4580.[185] Rather, this commenter believes that only payments to political parties or PACs where the covered member or a covered associate: (i) Directs the political party or PAC to make a contribution to an official of a government entity which the covered member is soliciting on behalf of an investment adviser; or (ii) knows that the political party or PAC is going to make a contribution to an official of a government entity which the covered member is soliciting on behalf of an investment adviser, should have to be maintained.[186] This commenter states that, while it appreciates FINRA's rationale for proposed Rule 4580, it believes the costs and burdens associated with the request far outweigh the benefits to FINRA in ensuring compliance with the rule and would lead to periodic "fishing expeditions" by FINRA examiners.[187]

In response, FINRA states that it disagrees with these comments and has determined to retain the recordkeeping requirements as proposed in FINRA Rule 4580.[188] FINRA notes that, as discussed in the Notice, payments to political parties or PACs can be a means for a covered member or covered associate to funnel contributions to a government official without directly contributing.[189] Therefore, FINRA states that it is proposing to require a covered member to maintain a record of all payments to political parties or PACs as such records would assist FINRA in identifying situations that might suggest an intent to circumvent the rule.[190]

H. Comments Regarding the De Minimis Exception Under Proposed Rule 2030(c) and FINRA's Responses

As discussed above, certain commenters raise concerns regarding the exception for *de minimis* contributions under proposed Rule 2030(c)(1) on First Amendment grounds.[191] In addition, one commenter requests that the $350 and $150 amounts "be raised substantially" in both the SEC Pay-to-Play Rule and in proposed Rule 2030(c)(1), and further requests that the $350 limitation on the proposed exception for returned contributions under proposed Rule 2030(c)(3) be eliminated in both the SEC Pay-to-Play Rule and in FINRA's proposed rule.[192]

In response, FINRA explains that its proposed rules must impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[193] Therefore, FINRA has proposed exceptions for *de minimis* contributions and returned contributions that are consistent with similar exceptions in the SEC Pay-to-Play Rule.[194] FINRA does not believe that raising the limits for the *de minimis* exception or eliminating the limit for returned contributions would impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[195]

I. Comments Regarding the Grandfathering of Existing Accounts and Contracts and FINRA's Responses

One commenter requests that FINRA clarify the application of the proposed rule to existing government entity accounts or contracts.[196] FSI requests that, in the event that FINRA does not amend the application of its proposed rule to covered investment pools (as requested by this same commenter), FINRA apply the proposed rule only to accounts and variable contracts opened after the effective date.[197]

In response, FINRA explains that, as discussed above, its proposed rules must impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[198] The Commission did not apply its rule only to contracts or accounts opened after the effective date of the rule.[199] FINRA also explains in the Notice that, if the Commission approves the proposed rule change, proposed Rule 2030(a) will not be triggered by contributions made prior to the rule's effective date, and that the rule will not apply to contributions made prior to the effective date by new covered associates to which the two years or, as applicable, six months "look back" applies.[200] FINRA states that the transition period—the time between the Commission approving the proposal and FINRA announcing the effective date of the rule—will provide member firms with time to identify their covered associates and government entity clients and to modify their supervisory systems to address new obligations under the rules.[201] Therefore, FINRA does not believe that limiting the application of its rule in the way suggested by FSI would impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers.[202]

J. Comments Regarding Application of the Proposed Rules to the Independent Business Model and FINRA's Responses

One commenter claims that its members "will face difficulties" in attempting to comply with the proposed rules, and that these difficulties stem, primarily, from a requirement for independent firms to implement a rule that is premised on the notion that solicitation of clients is performed pursuant to a centralized process controlled by the management of a registered investment adviser.[203] This same commenter claims that the "lack of clarity" as to the application of the SEC Pay-to-Play Rule to its members' independent business model, and the scope of government officials that trigger the requirements, has led some firms to adopt aggressive compliance programs that prohibit political contributions.[204]

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[184] *See id.* at 18.

[185] *See* CAI Letter 1.

[186] *See id.*

[187] *See id.*

[188] *See* FINRA Response Letter 2 at 20.

[189] *See id.* As FINRA explains in the Notice, a covered associate would include a PAC controlled by the covered member or any of its associates. FINRA states that it would consider a covered member or its covered associates to have "control" over a PAC if the covered member or covered associate has the ability to direct or cause the direction of governance or operations of the PAC. *See* Notice, 80 FR at 81653, 81660 (noting that this position is consistent with the position taken by the SEC in connection with the SEC Pay-to-Play Rule) (citing SEC Pay-to-Play Adopting Release, 75 FR at 41032).

[190] *See* FINRA Response Letter 2 at 20–21. FINRA states in the Notice that the proposed recordkeeping requirements are intended to allow FINRA to examine for compliance with its proposed pay-to-play rule, and the reference to indirect contributions in proposed Rule 4580(a)(4) is intended to include records of contributions or payments a covered member solicits or coordinates another person or PAC to make under proposed Rule 2030(b). *See* Notice, 80 FR at 81663.

[191] For a discussion of these First Amendment comments and FINRA's responses, *see* Section III.A, *supra.*

[192] *See* CAI Letter 1 (claiming that these contribution amounts fail to take inflation into consideration and are "unreasonably low").

[193] *See* FINRA Response Letter 2 at 19.

[194] *See id.*

[195] *See id.*

[196] *See* FSI Letter 1.

[197] *See id.*

[198] *See* FINRA Response Letter 2 at 16.

[199] *See id. See also* Notice, 80 FR at 81656.

[200] *See* Notice, 80 FR at 81656.

[201] *See* id. ("FINRA intends to establish an effective date that is no sooner than 180 days following publication of the Regulatory Notice announcing Commission approval of the proposed rule change, and no later than 365 days following Commission approval of the proposed rule change.").

[202] *See* FINRA Response Letter 2 at 16.

[203] *See* FSI Letter 1 (claiming FSI believes that the SEC Pay-to-Play Rule has inadvertently captured non-corrupting activity and fears that the proposed rule may do the same).

In response, FINRA states that, consistent with the SEC Pay-to-Play Rule, it has determined not to except from its proposed pay-to-play rule member firms engaged in the independent business model.[205] FINRA, however, states that, to the extent that interpretive questions arise regarding the application and scope of the provisions and terms used in the proposed rule change, FINRA will work with the industry and Commission to address the interpretive questions and provide additional guidance as needed.[206]

K. Comments Requesting More Stringent Requirements in the Proposed Rules and FINRA's Responses

Two commenters suggested that proposed Rule 2030 include more stringent requirements in certain respects.[207] First, both commenters request that FINRA expand the applicability of its proposed rules to include state-registered investment advisers.[208] More specifically, one of these commenters suggests that FINRA include state-registered investment advisers in its definition of "investment adviser" for the purposes of its proposed rule.[209] Although FINRA states in the Notice that relatively few state-registered investment advisers manage public pension plans,[210] one commenter believes that this alone does not justify permitting FINRA-member firms that do manage public pension plans, but happen to work with smaller investment advisers, to engage in pay-to-play activities with no repercussions.[211] Another commenter claims that state-registered investment advisers now include larger firms and, therefore, it is much more likely that state-registered investment advisers will manage or advise public pension plans or similar funds.[212]

In response, FINRA states that, as discussed in the Notice,[213] to remain consistent with the SEC Pay-to-Play Rule, FINRA has determined not to expand the scope of the proposed rule as suggested by commenters to include state-registered investment advisers in its definition of "investment adviser" for the purposes of its proposed rule.[214] As discussed in the Notice, FINRA explains that the Commission also declined to make a similar change to its proposed rule, stating that it was the Commission's understanding that few of these smaller firms manage public pension plans or other similar funds.[215]

Second, these two commenters request that FINRA include a mandatory disgorgement provision for violations of its proposed rule.[216] These commenters state that they are disappointed that FINRA removed the mandatory disgorgement provisions from the proposal as outlined in FINRA's *Regulatory Notice* 14–50.[217] These commenters believe that a mandatory disgorgement provision would act as a significant deterrent to engaging in pay-to-play schemes, and it should remain in FINRA's final rule.[218]

In response, FINRA states that, after considering similar comments made in response to its *Regulatory Notice* 14–50, in particular, that FINRA has authority to require disgorgement of fees in enforcement actions, FINRA determined not to include a disgorgement requirement in its proposal.[219] For those same reasons, which also are discussed in the Notice,[220] FINRA also has determined not to revise the proposal to include a disgorgement requirement.[221]

Finally, one commenter believes that the cooling-off period in the proposal should be at least four years.[222] PIABA believes that the two-year cooling-off period does not adequately reduce the incentive for FINRA member firms to make political contributions to obtain pay-to-play advantages.[223] PIABA states FINRA should start with the most comprehensive rule, and that it would welcome the deterrent effect of a four-year cooling off period.[224]

FINRA declines to make PIABA's suggested change.[225] FINRA explains that the proposed two-year time-out is consistent with the time-out period in the SEC's Pay-to-Play Rule and, FINRA believes that a two-year time-out period from the date of a contribution is sufficient to discourage covered members from engaging in pay-to-play practices.[226] As FINRA explains in the Notice, the two-year time-out in the proposed rule is intended to discourage covered members from participating in pay-to-play practices by requiring a cooling-off period during which the effects of a *quid pro quo* political contribution on the selection process can be expected to dissipate.[227]

IV. Discussion and Commission Findings

After carefully considering the proposed rule change, the comments submitted, and FINRA's responses thereto, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered national securities association.[228]

In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act.[229] Section 15A(b)(6), which governs registered national securities associations like FINRA, requires, among other things, that the association's rules be "designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, . . . to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest."[230] As discussed in more detail below, we believe that FINRA's proposal is consistent with Section 15A(b)(6). FINRA's proposed rule will address the regulatory concerns that underlie, and thus support the objectives of, the SEC Pay-to-Play Rule, discussed below, by discouraging FINRA member firms and certain of their covered associates from engaging in *quid pro quo* corruption that may create market distortions—when, for example, an investment adviser is chosen on the basis of a placement agent's political contributions rather than the adviser's merit. Such conduct impedes a free and open market, and may harm investors and the public interest if government entities, including public pension plans, and their beneficiaries receive inferior services or pay higher fees.[231] FINRA's proposed rule also promotes a free and open market and the protection of investors and the public interest by avoiding the outright ban on distribution and solicitation activity that would result if FINRA member firms were not "regulated person[s]" under the SEC Pay-to-Play Rule.[232] The fact that FINRA's proposed rule may have implications for a small subset of political contributions made by certain covered associates to certain elected officials does not somehow eliminate FINRA's ability to adopt rules pursuant to the Act, or the Commission's authority to approve such rules under Section 19(b)(2) of the Act.[233]

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[204] *See id.* (claiming that, absent clarity concerning the application of the proposed rule to the brokerage services provided to 403(b) and 457 plans, FSI's members will be faced with the choice of either adopting similarly aggressive policies or prohibiting sales to government-sponsored retirement plans).

[205] *See* FINRA Response Letter 2 at 18.

[206] *See id.*

[207] *See* NASAA Letter and PIABA Letter.

[208] *See* NASAA Letter and PIABA Letter.

[209] *See* NASAA Letter.

[210] *See* NASAA Letter and PIABA Letter.

[211] *See* PIABA Letter. Unless the commenter is discussing dually-registered intermediaries, we do not understand the commenter's reference to "FINRA-member firms that do manage public pension plans" as those plans are managed by investment advisers, not broker-dealers.

[212] *See* NASAA Letter.

[213] *See* Notice, 80 FR at 81652 n.26 (explaining that "consistent with the SEC Pay-to-Play Rule, the proposed rule would not apply to state-registered investment advisers as few of these smaller firms manage public pension plans or other similar funds"). *See also id.* at 81660 n.98 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41026).

[214] *See* FINRA Response Letter 2 at 10.

[215] *See* Notice, 80 FR at 81652 n.26. *See also id.* at 81660 n.98.

[216] *See* NASAA Letter and PIABA Letter.

[217] *See* NASAA Letter and PIABA Letter.

[218] *See* NASAA Letter and PIABA Letter.

[219] *See* FINRA Response Letter 2 at 19–20.

[220] *See* Notice, 80 FR at 81662 (noting, for example, ICI's comment made in connection with *Regulatory Notice* 14–50 that "including disgorgement as a penalty is not necessary given that the SEC and FINRA both have full authority to require disgorgement of fees, and indeed, disgorgement has been the penalty universally applied (along with additional penalties) in enforcement actions under existing pay-to-play rules, such as MSRB Rule G–37 and SEC Rule 206(4)–5").

[221] *See* FINRA Response Letter 2 at 20.

[222] *See* PIABA Letter.

[223] *See id.*

[224] *See id.*

[225] *See* FINRA Response Letter 2 at 10.

[226] *See id.*

[227] *See* Notice, 80 FR at 81651. As the Commission explained, the two-year "cooling-off period" is not a penalty but, rather, is intended to be a period during which any effects of a *quid pro quo* are expected to dissipate. *See* SEC Pay-to-Play Adopting Release, 75 FR at 41026 n.104.

[228] In approving this proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. In this regard, the Commission considered FINRA's extensive discussion of these effects in its Notice and FINRA's response to comments on that discussion. Moreover, the Commission observes that, in response to the Commission's Notice, no commenter suggested that FINRA's analysis was incorrect or incomplete, or that the proposed rule change would have a negative effect on efficiency, competition, or capital formation. *See* 15 U.S.C. 78c(f).

[229] 15 U.S.C. 78*o*–3(b)(6).

As support for the need for the proposed rule, FINRA outlined certain regulatory concerns in the Notice that also were identified by the Commission in connection with its adoption of the SEC Pay-to-Play Rule.[234] These concerns, which also implicate the investor and public interest protections described in Section 15A(b)(6) of the Act, recognize the central role intermediaries, such as "solicitors" or "placement agents," have played in actions that the Commission and other authorities have brought involving pay-to-play schemes.[235] FINRA also acknowledges the Commission's observation of how investment advisers, in several instances, allegedly made significant payments to placement agents and other intermediaries to influence the award of advisory contracts.[236] Moreover, FINRA points out the difficulties that investment advisers face in monitoring or controlling the activities of their third-party solicitors.[237]

As we explained in adopting the SEC Pay-to-Play Rule, public pension plans are particularly vulnerable to pay-to-play practices, and we have been particularly concerned that the engagement of placement agents who have made political contributions to key officials is viewed by investment advisers as a necessary step to securing a contract with a public pension plan.[238] In connection with the SEC Pay-to-Play Rule, we initially proposed a complete bar on investment advisers engaging third parties to solicit government clients on their behalf because of concerns about investment advisers' use of third-party solicitors and placement agents to engage in pay-to-play activities.[239] However, persuaded by commenters, we revised the proposed SEC Pay-to-Play Rule to permit advisers to make payments to certain "regulated persons" to solicit government clients on their behalf, provided that they are themselves subject to prohibitions against participating in pay-to-play practices, are subject to Commission oversight and, in the case of broker-dealers, the oversight of a registered national securities association such as FINRA.[240] FINRA agreed and informed us that it would prepare rules for our consideration that would prohibit its members from soliciting advisory business from a government entity on behalf of an adviser unless they comply with pay-to-play restrictions.[241]

Pay-to-play practices are harmful. They create an impediment to a free and open market by, for example, distorting the investment adviser selection process from one that is based on merit, performance and cost, to one that is influenced by a placement agent's contributions to the campaigns of government officials who are responsible for, or can influence the outcome of, selecting an investment adviser.[242] As a result of this distortion, government entities, including pension funds, and their citizen beneficiaries may be harmed by receiving inferior services or paying higher fees.[243] Investors and the public interest ultimately suffer, including taxpayers, residents who rely on municipal services, and the beneficiaries of public pension funds, such as firemen, police officers, teachers, and other civil servants.[244] Investment advisers also are harmed because their ability to participate in the market is impeded unless they are willing to engage in pay-to-play practices by, for example, hiring placement agents that make certain political contributions.[245]

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[230] *Id.*

[231] *See* FINRA Response Letter 2 at 8. *See also* Notice, 80 FR at 81651, 81656 (discussing the regulatory objectives of and statutory basis for the proposal).

[232] *See* FINRA Response Letter 2 at 5 ("FINRA believes that the proposed rule change is a more effective response to the issues addressed in the SEC Pay-to-Play Rule than a complete ban on solicitation."). *See also* Notice, 80 FR at 81652, 81656 (discussing the regulatory objectives of and statutory basis for the proposal).

[233] While FINRA's proposed rule does not bar member firms and their covered associates from making contributions, it may affect the propensity of member firms and certain employees to make the subset of contributions that would trigger the two-year time-out. FINRA's rule does not impose a requirement that member firms publicly disclose political contributions.

[234] *See* Notice, 80 FR at 81651, nn.12–14 (discussing concerns the Commission identified in the SEC Pay-to-Play Rule Adopting Release, 75 FR at 41037).

[235] *See* Notice, 80 FR at 81651. *See also id.* at nn.10–11 (explaining that "solicitors" typically locate investment advisory clients on behalf of an investment adviser, and that "placement agents" typically specialize in finding investors, often institutional investors or high net worth investors, that are willing and able to invest in a private offering of securities on behalf of the issuer of such privately offered securities) (citing Advisers Act Release No. 2910 (Aug. 3, 2009), 74 FR 39840, 39853 n.137 (Aug. 7, 2009) (Political Contributions by Certain Investment Advisers)).

[236] *See* Notice, 80 FR at 81651. *See also e.g.,* SEC Pay-to-Play Adopting Release, 75 FR at 41037.

[237] *See* Notice, 80 FR at 81651. *See also* SEC Pay-to-Play Adopting Release, 75 FR at 41032 n.182, 40137 n.266 (acknowledging commenters' concerns regarding the difficulties that advisers may have when monitoring the activities of their third-party solicitors).

[238] *See* SEC Pay-to-Play Adopting Release, 75 FR at 41019–20, nn.16–25 (collecting examples of SEC litigation releases as well as state and federal criminal actions with pay-to-play schemes involving placement agents among other intermediaries). *See also id.* at 40137, n.262 (collecting examples of state and local legislative actions undertaken to prohibit or regulate pay-to-play practices involving placement agents in response to concerns about pay-to-play activities in their jurisdictions).

[239] *See id.* at 41037 nn.259–68 (discussing the Commission's observations in the SEC Pay-to-Play Rule proposing release).

[240] *See id.* at 41041.

[241] *See* Notice, 80 FR at 81651 n.15 (citing a letter from Richard G. Ketchum, Chairman and Chief Executive Officer, FINRA, to Andrew J. Donohue, Director, Division of Investment Management, Commission (Mar. 15, 2010) ("Ketchum Letter"), available at *http://www.sec.gov/comments/s7-18-09/s71809-260.pdf* (stating that FINRA "believe[s] that a regulatory scheme targeting improper pay to play practices by broker-dealers acting on behalf of investment advisers is . . . a viable solution to a ban on certain private placement agents serving a legitimate function")). FINRA also notes that in developing its proposal it intended to draw closely upon all the substantive and technical elements of the Commission's rule as well as FINRA's regulatory expertise in examining and enforcing the MSRB rules, upon which the SEC Pay-to-Play Rule is based. *See* Ketchum Letter. *See also* SEC Pay-to-Play Adopting Release, 75 FR at 41042 n.317 (discussing same).

[242] *See, e.g.,* SEC Pay-to-Play Adopting Release, 75 FR at 41023, 41039.

[243] SEC Pay-to-Play Adopting Release, 75 FR at 41019.

The Commission also believes that the stealth in which pay-to-play practices occur and the inability of markets to properly address these practices argue strongly for rules like the SEC Pay-to-Play Rule and FINRA's proposal.[246] Pay-to-play practices create a "collective action" problem in two respects: (1) Government officials who participate in such activities have an incentive to continue to accept contributions to support their campaigns for fear of being disadvantaged relative to their opponents; and (2) investment advisers have an incentive to participate out of concern that they may be overlooked if they fail to make a contribution.[247]

We believe that application of FINRA's proposed pay-to-play rules will effectively discourage covered members and their covered associates who act as placement agents for investment advisers from participating in pay-to-play practices because their political contributions or payments will be subject to restrictions similar to those imposed on investment advisers under the SEC Pay-to-Play Rule.[248] The Commission therefore believes that FINRA's proposed rule change will help address the concerns identified in the SEC Pay-to-Play Rule Adopting Release regarding the distortion of the investment advisory market.[249] As a result, like the SEC Pay-to-Play rule, FINRA's proposal should help protect investors and the public interest by, among other things, reducing the costs to plans and their beneficiaries of inferior asset management services arising from adviser selection based on a placement agent's political contributions rather than prudential investment considerations.[250] Further, in the Commission's view, FINRA's proposed rule strikes an appropriate balance in addressing these regulatory concerns by providing for FINRA member firms to be "regulated person[s]" under the SEC Pay-to-Play Rule.[251] As a result, investment advisers will be able to continue to benefit from the use of placement agents in obtaining investment advisory business with government entities without political contributions distorting the process by which a government entity, such as a public pension fund, selects an adviser.[252] The two-year time-out period imposed by the proposed rule change is not a penalty but, rather, is intended to discourage participation in pay-to-play practices by requiring a "cooling-off period" during which the effects of a *quid pro quo* political contribution on the selection process are expected to dissipate.[253] This time-out will help promote fair competition in the market and protect public pension funds and investors by curbing fraudulent conduct resulting from pay-to-play practices.[254] In addition, according to FINRA, the proposal can be expected to help promote competition by allowing more third-party solicitors to participate in the market for solicitation services, which in turn may reduce costs to investment advisers and improve competition for advisory services.[255] For these reasons and as discussed throughout, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act.[256]

The Commission notes that most commenters to the Notice[257] and some of the commenters responding to the Order Instituting Proceedings[258] generally express support for FINRA's proposal. For example, one commenter states that it is pleased that, like the SEC and the MSRB, FINRA is adopting rules to govern the activities of its members that solicit government clients on behalf of an investment adviser and also is pleased that FINRA's proposal is designed to complement, and be consistent with, the SEC's pay-to-play rule.[259] Similarly, another commenter states that, although it requests certain revisions, it also supports FINRA's attempt to deter pay-to-play activity among covered members and supports the regulatory objectives underlying the Proposed Rules.[260]

The Commission acknowledges the concerns and questions raised by some commenters, which are outlined in further detail above in Section III. As discussed below, the Commission believes, however, that FINRA has responded to the commenters' concerns and questions in light of, among other things, the regulatory framework established by the SEC Pay-to-Play Rule, which provides that FINRA's proposed rules must impose substantially equivalent or more stringent restrictions on its members than the SEC Pay-to-Play Rule imposes on investment advisers for FINRA members to be "regulated persons" under the SEC Pay-to-Play Rule.

A. Comments Concerning the First Amendment and Related Concerns

Several commenters express the view that FINRA's proposed rule violates the First Amendment.[261] The Commission is sensitive to the constitutional concerns raised by the commenters, but after careful consideration of their arguments, for the reasons discussed below, concludes that FINRA's rule is consistent with the First Amendment.

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[244] SEC Pay-to-Play Adopting Release, 75 FR at 41019 (noting that the management of public pension plans "most significantly . . . affects taxpayers and the beneficiaries of these funds, including the millions of present and future State and municipal retirees who rely on the funds for their pensions and other benefits").

[245] *See, e.g.,* SEC Pay-to-Play Adopting Release, 75 FR at 41023, 41039 (explaining that "pay to play practices may hurt smaller advisers that cannot afford the required contributions. Curtailing pay to play arrangements enables advisory firms, particularly smaller advisory firms, to compete on merit, rather than their ability or willingness to make contributions").

[246] *See* SEC Pay-to-Play Adopting Release, 75 FR at 40122–23. *See also* FINRA Response Letter at 6 (noting that, as explained in *Blount,* "no smoking gun is needed;" however, "where, as here, the conflict of interest is apparent, the likelihood of stealth great, and the [Commission's] purpose prophylactic").

[247] *See* FINRA Response Letter at 9; SEC Pay-to-Play Adopting Release, 75 FR at 40122.

[248] *See* Notice, 80 FR at 81651.

[249] *See* FINRA Response Letter at 9 (stating that "[f]or example, the proposed rule change is reasonably designed to address the distortion of the investment advisory market and collective action problems created by pay-to-play practices"). As the Commission has explained, by addressing distortions in the process by which investment advisers are selected regarding public investments, pay-to-play rules provide important protections to public pension plans and their beneficiaries, as well as participants in other important plans or programs sponsored by government entities. *See* SEC Pay-to-Play Adopting Release, 75 FR at 41023, 41054.

[250] *See* SEC Pay-to-Play Adopting Release, 75 FR at 41039.

[251] *See, e.g.,* FINRA Response Letter at 5 ("FINRA believes that the proposed rule change is a more effective response to the issues addressed in the SEC Pay-to-Play Rule than a complete ban on solicitation.") *See also* Notice, 80 FR at 81652, 81656 (discussing the regulatory objectives of and statutory basis for the proposal).

[252] *See, e.g.,* FINRA Response Letter 2 at 8 ("The proposed rule change accomplishes these goals by allowing member firms to continue to engage in distribution or solicitation activities for compensation with governmental entities on behalf of investment advisers, while at the same time deterring member firms from engaging in pay-to-play practices.").

[253] *See* Notice, 80 FR at 81651. *See also* SEC Pay-to-Play Adopting Release, 75 FR at 41026 n.104.

[254] *See* Notice, 80 FR at 81657.

[255] *See id.*

[256] *See* 15 U.S.C. 78*o*–3(b)(6).

[257] *See* CAI Letter 1; CAI Letter 2; FSI Letter 1; ICI Letter; NAIFA Letter; NASAA Letter; and PIABA Letter.

[258] *See* FSI Letter 2 (claiming that the proposal creates "compliance uncertainties" for FSI's members, but noting that FSI "support[s] regulatory efforts to combat pay-to-play corruption activity").

[259] *See* ICI Letter.

[260] *See* CAI Letter 1 (recognizing "the challenges in crafting the Proposed Rules so that they reach all of the activity sought to be eliminated without also prohibiting activity that is harmless").

[261] *See* CCP Letter 1; FSI Letter 1; FSI Letter 2; and State Parties Letter 1. *See also* CCP Letter 2; CCP Letter 3; Moran Letter and State Parties Letter 2.

FINRA's rule, which focuses on covered members who serve as placement agents, tracks the SEC Pay-to-Play Rule for investment advisers, which, in turn, tracks the MSRB's pay-to-play rule, Rule G–37, which the D.C. Circuit upheld against First Amendment challenge in 1995.[262] The Supreme Court has issued several decisions regarding political speech since *Blount* was decided,[263] and none of these decisions call into question *Blount's* holding that a tailored pay-to-play rule, which is nearly identical in purpose and form to FINRA's proposed rule and which also furthers an important public interest, is constitutional. Indeed, the *en banc* D.C. Circuit recently and unanimously upheld a broader pay-to-play restriction—a bar on all contributions to federal candidates by federal contractors—in its decision in *Wagner* that analyzed the post-*Blount* Supreme Court decisions and cited *Blount* with approval.[264] Various pay-to-play restrictions imposed by other jurisdictions also have withstood First Amendment challenge in recent years.[265]

Decisions like *Wagner* confirm that even an outright limitation on contributions—as opposed to FINRA's rule, which may indirectly discourage contributions—is permissible if it is justified by a sufficiently important government interest and is closely drawn to avoid unnecessary abridgement of the type of political speech represented by a political contribution.[266] We believe that FINRA's proposed rule serves a vitally important governmental interest: Discouraging a specific type of *quid pro quo* corruption in which political contributions made by placement agents may influence the award of investment advisory business by government entities. The Supreme Court has long held that halting *quid pro quo* corruption is an important government interest that justifies limitations—or outright bans—on contributions.[267]

We do not understand FINRA to be engaging in broad electoral reform or trying to clean up the electoral process. Rather, to avoid the outright ban on placement agent activity resulting from FINRA member firms not being "regulated person[s]" under the SEC Pay-to-Play Rule, the two-year time-out in FINRA's proposal, like the SEC Pay-to-Play Rule, discourages *quid pro quos* that affect government entities, including public pension funds, served by investment advisers. *Quid pro quos* involving placement agents, who make contributions to certain elected officials and then assist investment advisers in obtaining business from the government entities those officials serve may be: Fraudulent, run counter to just and equitable principles of trade, impede a free and open market, and harm investors and the public interest.[268] When pay-to-play is a factor in the selection or retention of an investment adviser—when the adviser is chosen on the basis of a placement agent's political contributions rather than its merit—the most qualified adviser may not be hired, which may lead to inferior performance and payment of higher fees.[269] Ultimately, taxpayers and fund beneficiaries suffer the harm. Moreover, pay-to-play distorts free and open markets by requiring investment advisers and their placement agents to "play the game" or risk being left out.[270] In short, while FINRA's rule resembles other contribution limitations by serving a government interest in discouraging *quid quo pro* corruption, it is a targeted effort that should protect investors and the public by promoting the integrity of the investment advisory market.

FINRA's proposed rule advances this important governmental interest because the two-year time-out discourages pay-to-play. As explained above, pay-to-play has been and is a serious problem when placement agents assist investment advisers in obtaining advisory business from government entities.[271] Placement agents "played a central role in actions that [the Commission] and other authorities have brought involving pay-to-play schemes," and, in several instances, advisers used placement agents, who had made campaign contributions to elected officials, to influence the award of investment advisory contracts.[272] Most notably, Alan Hevesi, the Comptroller of New York State who was responsible for investment of state pension funds, accepted campaign contributions from a placement agent and steered over $250 million in pension funds to investment advisers that had retained the placement agent.[273]

In response to these incidents, the Commission proposed a ban on the use of placement agents by investment advisers and ultimately adopted a final rule that permitted use of placement agents so long as they were "regulated persons" governed by the type of pay-to-play rule that FINRA has proposed here.[274] FINRA is not alone in addressing these issues. For example, several State and local governments have barred or restricted placement agents from playing a role in the contracting process.[275] Although the Supreme Court has never required a certain amount of past *quid pro quo* corruption to sustain a contribution limitation, there is more than sufficient evidence of pay-to-play practices to support FINRA's rule.[276]

The contours of FINRA's proposed rule reflect how pay-to-play practices involving placement agents affect the hiring and retention of investment advisers by State and local pension funds. One scenario implicated by FINRA's rule (and reflected in the

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[262] *Blount* v. *SEC,* 61 F.3d 938 (D.C. Cir. 1995), *cert. denied,* 517 U.S. 1119 (1996). One significant difference between the MSRB rule, on one hand, and the SEC's and FINRA's rules, on the other, is that the MSRB rule requires the public disclosure of political contributions whereas the SEC's and FINRA's rules do not.

[263] *See, e.g., McCutcheon* v. *FEC,* 134 S. Ct. 1434 (2014); *Citizens United* v. *FEC,* 558 U.S. 310 (2010); *Davis* v. *FEC,* 554 U.S. 724 (2008); *FEC* v. *Wisc. Right To Life, Inc.,* 51 U.S. 449 (2007); *Randall* v. *Sorrell,* 548 U.S. 230 (2006); *FEC* v. *Beaumont,* 539 U.S. 146 (2003); *Nixon* v. *Shrink Mo. Gov't PAC,* 528 U.S. 377 (2000).

[264] *Wagner* v. *FEC,* 793 F.3d 1 (D.C. Cir. 2015) (en banc), *cert. denied sub nom., Miller* v. *FEC,* 136 S. Ct. 895 (2016).

[265] *See, e.g., Yamada* v. *Snipes,* 786 F.3d 1182 (9th Cir.), *cert. denied,* 136 S. Ct. 569 (2015); *Preston* v. *Leake,* 660 F.3d 726, 729–30, 736 (4th Cir. 2011); *Ognibene* v. *Parkes,* 671 F.3d 174, 179–80 (2d Cir. 2011); *Green Party of Connecticut* v. *Garfield,* 616 F.3d 189, 200 (2d Cir. 2010).

[266] *Wagner,* 793 F.3d at 6–8. We note that FINRA's rule is not an absolute bar on contributions, but the two-year time-out may have the effect of discouraging member firms and certain covered associates who may act as placement agents for investment advisers from making certain contributions to certain covered officials. To the extent that the commenters suggest that such an indirect limitation on contributions would be reviewed by a court under strict scrutiny, they misstate applicable Supreme Court precedent, which has maintained that limitations on contributions are reviewed under a more intermediate form of scrutiny because "[c]ontribution limits impose a lesser restraint on political speech" that permits "'symbolic expression of support evidence by a contribution" but do not "'in any way infringe the contributor's freedom to discuss candidates and issues.'" *McCutcheon,* 134 S. Ct. at 1444, quoting *Buckley* v. *Valeo,* 424 U.S. 1, 21 (1976).

[267] *McCutcheon,* 134 S. Ct. at 1452; *Buckley,* 424 U.S. at 27–28 (1976).

[268] *Blount,* 61 F.3d at 944–48. *See also* 15 U.S.C. 78*o*–3(b)(6).

[269] SEC Pay-to-Play Adopting Release, 75 FR at 41022, 41053–54.

[270] *Id.* at 41019, 41022, 41053. *See also Blount,* 61 F.3d at 945–46.

[271] SEC Pay-to-Play Adopting Release, 75 FR at 41019–20. Pay-to-play that affects State and local pension funds is not limited to the investment advisory context.

[272] SEC Pay-to-Play Adopting Release, 75 FR at 41019–20, 41037.

[273] *Id.* at 41019–20.

[274] *Id.* at 41037–42.

[275] *Id.* at 41037 n. 262.

[276] *McCutcheon,* 134 S. Ct. at 1445, 1458; *Nixon,* 528 U.S. at 390–91; *Buckley,* 424 U.S. at 29–30.

Hevesi matter) involves an investment adviser that seeks business from a State pension fund and retains a firm, or an individual at a firm, that has made contributions to an elected official responsible for selecting investment advisers.[277] The elected officials who participate have no incentive to stop accepting contributions for fear of being disadvantaged relative to their opponents. Similarly neither the placement agents that make the contributions nor the investment advisers that hire the placement agents have an incentive to stop out of concern that if they abstain, their competitors will continue to engage in the practice profitably and without adverse consequences.[278] FINRA's rule should resolve this collective-action problem by interposing a time-out that creates a disincentive to engage in pay-to-play.

The proposed FINRA rule, like the SEC Pay-to-Play Rule that it is modeled on, is a tailored solution to a particularly pernicious form of *quid pro quo* corruption that affects the beneficiaries of public pension funds, such as teachers, law enforcement officers, firefighters, and other public servants, as well as the beneficiaries of other collective government funds, including participant-directed plans such as 403(b), 457 and 529 plans. The proposed FINRA rule would affect a small segment of the electorate: In general, member firms acting as placement agents for investment advisers seeking to obtain advisory business from government entities. And the proposed FINRA rule would affect only a small number of elected officials—those who are responsible for or have authority to appoint any person who is responsible for or can influence the outcome of the hiring of an investment adviser by a government entity—and has no bearing on the vast majority of elections where the elected office's scope of authority does not encompass the awarding of investment advisory contracts. Moreover, the proposed FINRA rule's *de minimis* exception permits some campaign contributions to be made in all instances without triggering the time-out—thus allowing "the symbolic expression of support evidenced by a contribution"—and it does not restrict other forms of political speech, such as independent expenditures.[279]

B. Comments Regarding the Scope and Coverage of the Proposal

As discussed in detail above, the commenters raise several concerns regarding the scope and coverage of the proposed rules, including with respect to: The inclusion of variable annuities and mutual funds;[280] the inclusion of distribution activities;[281] the application to covered investment pools;[282] the level of the *de minimis* contribution exception and the returned contribution exception;[283] the inclusion of the independent business model;[284] and the application to existing contracts or accounts.[285] FINRA generally responded that its proposed rules are designed to be at least as stringent as the SEC Pay-to-Play Rule so that FINRA's member firms will meet the definition of "regulated persons" such that they are subject to rules that impose substantially equivalent or more stringent restrictions on its members than the SEC Pay-to-Play Rule imposes on investment advisers.[286]

As noted above, the SEC Pay-to-Play Rule, in part, prohibits any investment adviser covered under the rule or any of its covered associates from providing or agreeing to provide, directly or indirectly, payment to any person to solicit a government entity for investment advisory services on behalf of the investment adviser unless such person is a "regulated person," as defined under the rule.[287] The definition of "regulated person" includes a FINRA member firm, provided that: (a) FINRA rules prohibit member firms from engaging in distribution or solicitation activities if political contributions have been made; and (b) the Commission finds, by order, that such rules impose substantially equivalent or more stringent restrictions on member firms than the SEC Pay-to-Play Rule imposes on investment advisers and that such rules are consistent with the objectives of the SEC Pay-to-Play Rule.[288] Thus, any changes to the proposed rules that would result in FINRA's rules not being found to impose at least substantially equivalent restrictions on its member firms and to be otherwise consistent with the objectives of the SEC Pay-to-Play Rule would result in a ban on such activity.

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[277] SEC Pay-to-Play Adopting Release, 75 FR at 41019–20 & nn.18–20 (citing examples).

[278] *Id.* at 41022, 41040, 41053. *See also Blount,* 61 F.3d at 945–46. Even if the public is aware of the *quid pro quo* relationship, there is little that can be done because the official is compromised by the receipt of the contribution, and beneficiaries of a pension fund cannot easily shift their assets out of the fund, reverse the hiring decision, or remove the official. *Id.* at 41027. *See also id.* at 41053 n.459.

[279] *McCutcheon,* 134 S. Ct. at 1444, quoting *Buckley,* 424 U.S. at 21 (internal quotation marks omitted).

[280] *See* CAI Letter 1 and FSI Letter 1. *See also* CAI Letter 2 (reflecting CAI's suggested revisions to certain language in some of FINRA's proposed rules). In FINRA's view, because the Commission did not exclude specific products from the SEC Pay-to-Play Rule, such as variable annuities or mutual funds, excluding specific products from its proposed rule would not satisfy the Commission's stringency requirements. *See* FINRA Response Letter 2 at 16.

[281] *See* CAI Letter 1. *See also* CAI Letter 2 (reflecting CAI's suggested revisions to certain language in some of FINRA's proposed rules). FINRA notes that, among other things, language in the SEC Pay-to-Play Rule Adopting Release supports the inclusion of "distribution" activities by broker-dealers in FINRA's proposed Rule 2030(a). *See Notice, 80 FR* at 81660–61 (citing SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 n.298 where, according to FINRA, the Commission "clarif[ied] under what circumstances distribution payments would violate the SEC's Pay-to-Play Rule"). FINRA believes that based on the Commission's definition of "regulated person" in the SEC's Pay-to-Play Rule, as well as the Commission's discussion regarding the treatment of distribution fees paid pursuant to a 12b–1 plan as compared to legitimate profits, its proposed rule must apply to member firms engaging in distribution activities. *See* FINRA Response Letter 2 at 12 (citing Notice, 80 FR at 81660–61) and FINRA Response Letter 2 at 12 n.53 (explaining that the SEC Pay-to-Play Rule defines a "regulated person" to include a member firm, provided that FINRA rules prohibit member firms from engaging in *distribution* or solicitation activities if political contributions have been made, and citing SEC Pay-to-Play Rule 206(4)–5(f)(9)(ii)(A)) (emphasis in original).

[282] *See* CAI Letter 1; FSI Letter 1; FSI Letter 2. FINRA clarifies that it is not intending in this proposal to re-characterize broker-dealers' selling interests in variable annuities, mutual funds, and private funds as soliciting an investment advisory relationship with investors who invest in those products. *See* FINRA Response Letter 2 at 14–15 (noting, for example, that the applicability of proposed FINRA Rule 2030(d) is for purposes of FINRA's pay-to-play rule only). FINRA also explains that FINRA Rule 2030(d) is modeled on a similar provision in the SEC Pay-to-Play Rule, Rule 206(4)–5(c) and, as such, proposed FINRA Rule 2030(d) is intended to extend the protections of the proposed rule to government entities that access the services of investment advisers through hedge funds and other types of pooled investment vehicles sponsored or advised by investment advisers. *See* FINRA Response Letter 2 at 15 (noting that when adopting SEC Pay-to-Play Rule 206(4)–5(c), the Commission stated that although "an investment in a pooled investment vehicle may not involve a direct advisory relationship with a government sponsored plan [that] does not change the nature of the fraud or the harm that may be inflicted as a consequence of the adviser's pay-to-play activity") (quoting SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044–45). Finally, FINRA notes that the applicability of proposed FINRA Rule 2030(d) is for purposes of FINRA's pay-to-play rule only. *See* FINRA Response Letter 2 at 15.

[283] *See* CAI Letter 1. In response, FINRA explains that it has proposed exceptions for *de minimis* contributions and returned contributions that are consistent with similar exceptions in the SEC Pay-to-Play Rule as FINRA's proposed rules must impose substantially equivalent or more stringent restrictions on member firms as the SEC Pay-to-Play Rule imposes on investment advisers. FINRA does not believe that raising the limits for the *de minimis* exception or eliminating the limit for returned contributions would satisfy the Commission's stringency requirements set forth in the SEC Pay-to-Play Rule.

[284] *See* FSI Letter and FSI Letter 2. FINRA explains that the Commission did not exempt application of the rule for firms engaged in the independent business model. *See* FINRA Response Letter 2 at 16. As a result, in FINRA's view, excluding independent business model firms from its proposed rule would not satisfy the Commission's stringency requirements, although FINRA is willing to work with the industry and Commission to address the interpretive questions and provide additional guidance as needed.

[285] *See* FSI Letter 1. In response, FINRA explains that the Commission did not apply its rule only to contracts or accounts opened after the effective date of the rule; therefore, FINRA does not believe that limiting the application of its rule in the way suggested by FSI would satisfy the Commission's stringency requirements set forth in the SEC Pay-to-Play Rule. However, FINRA also explains that, if the Commission approves the proposed rule change, proposed Rule 2030(a) will not be triggered by contributions made prior to the rule's effective date, and that the rule will not apply to contributions made prior to the effective date by new covered associates to which the two years or, as applicable, six months "look back" applies. *See* Notice, 80 FR at 81656.

[286] *See, e.g.,* FINRA Response Letter 2 at 4, 16.

[287] *See* Notice, 80 FR at 81650 n.6, 81656. *See also* 17 CFR 275.206(4)–5(a)(2)(i)(A).

The Commission believes that it is appropriate and consistent with Section 15A(b)(6) of the Act for FINRA to design its proposed rules to have the same scope and provisions as the SEC Pay-to-Play Rule. If the Commission were unable to make the required stringency finding, this would result in FINRA member firms not being a "regulated person" under the SEC Pay-to-Play Rule and therefore prohibited from receiving compensation for engaging in distribution and solicitation activities with government entities on behalf of investment advisers.[289]

One commenter states that the proposal is ambiguous regarding the term "distribution" activities in Rule 2030(a).[290] This term in FINRA's proposed rule is taken directly from the definition of "regulated person" in the SEC Pay-to-Play Rule.[291] Although the term "distribution" is not defined specifically in the SEC Pay-to-Play Rule, to preserve the identified benefits of the rule, the Commission interprets the term broadly in the context of the SEC Pay-to-Play Rule to mean generally engaging in any activity that is primarily intended to result in the sale of securities.[292] In view of the Commission's prior statements regarding the term, including those contained in the SEC Pay-to-Play Rule Adopting Release,[293] we believe the term is not ambiguous and could be applied by FINRA members for purposes of the proposed rule in a way that is consistent with the prophylactic nature of the proposal. However, we note that in connection with adopting the SEC Pay-to-Play Rule, the Commission did clarify under what circumstances distribution payments would violate the SEC's Pay-to-Play Rule.[294] For example, the Commission explained that mutual fund distribution fees are typically paid by the fund from fund assets pursuant to a 12b–1 plan and generally would not constitute payment by the fund's adviser; therefore, such payments would not be prohibited under Rule 206(4)–5.[295] The Commission also explained that where an adviser pays for the fund's distribution out of its "legitimate profits," the rule would generally be implicated.[296] Based on the foregoing, we believe it is appropriate for FINRA not to have specifically defined the term "distribution" activities for purposes of its proposal.

One commenter claims that, among other things, the "lack of clarity as to the application of the SEC Pay-to-Play Rule to [its] members' business model, and the scope of government officials that trigger the requirements, has led some firms to adopt aggressive compliance programs that prohibit political contributions." [297] As discussed above, FINRA states that, consistent with the SEC Pay-to-Play Rule, it has determined not to except from its proposed pay-to-play rule member firms that use an independent business model.[298] We note that FINRA's rules and the federal securities laws do not distinguish so-called independent business model firms from other broker-dealer business models.[299] Rather, although a broker-dealer may organize its operations under a variety of business models, and different business models may present unique compliance challenges, it is up to the broker-dealer to sufficiently discharge its regulatory obligations in light of the business model it has elected, and to tailor its supervisory system appropriately so that it is reasonably designed [300] to achieve compliance with applicable federal securities laws and regulations and FINRA rules.[301]

We also note that FINRA has committed to working with the industry and the Commission to address interpretive questions that may arise regarding the application and scope of the provisions and terms used in the proposed rule change and to provide additional guidance as needed.[302]

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[288] *See* Notice, 80 FR at 81650 n.6. *See also* SEC Pay-to-Play Rule 206(4)–5(f)(9). The definition of "regulated person" also includes SEC-registered investment advisers and SEC-registered municipal advisors, subject to specified conditions.

[289] *See* Notice, 80 FR at 81650 n.6. *See also id.* at 81651, 81656 (discussing the regulatory objectives of and statutory basis for the proposal).

[290] *See* CAI Letter 1.

[291] A "regulated person," as defined in the SEC Pay-to-Play Rule, includes a FINRA member firm, provided that, among other things, FINRA rules "prohibit member firms from engaging in *distribution* or solicitation activities if certain political contributions have been made." 17 CFR 275.206(4)–5(f)(9)(ii) (emphasis added).

[292] By way of example in other contexts, the Commission has recognized that, because new distribution activities may continuously evolve in the future, it would be impracticable to develop, for example, an all-inclusive definition or list of such activities and related expenses, and declined to do so when it adopted the SEC Pay-to-Play Rule. *See* Bearing of Distribution Expenses by Mutual Funds, Investment Company Act Release No. 11414 (Oct. 28, 1980), 45 FR 73898, 73903 (Nov. 7, 1980) ("Rule 12b–1 Adopting Release"). *See also* 17 CFR.12b–1(a)(2) (explaining, in the context of registered open-end funds, that one will be deemed to be acting as a distributor of securities if they engage in "any activity which is primarily intended to result in the sale of shares issued by such [fund], including, but not necessary limited to, the compensation of underwriters, dealers and other sales personnel, the printing and mailing of prospectuses to other than current shareholders, and the printing and mailing of sales literature").

[293] *See infra* notes 294–296 and accompanying text.

[294] *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 n.298. *See also* FINRA Response Letter 2 at 12 (citing Notice, 80 FR at 81660–61).

[295] *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 n.298 (citing Rule 12b–1 Adopting Release).

[296] *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41040 (citing Rule 12b–1 Adopting Release).

[297] *See* FSI Letter 1 (claiming FSI believes that the SEC Pay-to-Play Rule has inadvertently captured non-corrupting activity and it fears that the proposed rule may do the same).

[298] *See* FINRA Response Letter 2 at 18.

[299] While a firm may accept independent contractor status for purposes other than the federal securities laws, such treatment does not alter such person's status as a person associated with a broker or dealer or the firm's responsibility to supervise under the federal securities laws. *See, e.g., Hollinger* v. *Titan Capital Corp.*, 914 F.2d 1564, 1572–76 (9th Cir. 1990) (*en banc*) (explaining that, even if a broker-dealer and registered representative contractually agree that a representative is an independent contractor, the broker-dealer is still required to supervise its representatives).

[300] *See* FINRA Rule 3110(a) ("Each member shall establish and maintain a system to supervise the activities of each associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations and with applicable FINRA rules.") and Exchange Act Section 15(b)(4)(E), 15 U.S.C. 78o(b)(4)(E) (authorizing the Commission to sanction a broker-dealer that "has failed reasonably to supervise, with a view to preventing violations of" the federal securities laws and rules and regulations thereunder).

[301] Giving guidance on its supervision rule, FINRA (then-NASD) noted that to fulfill its obligations to establish and maintain a supervisory system, a member firm must determine the types of business it conducts, how the firm is organized and operated, and the current regulatory requirements. *See* NASD Notice to Members 99–45 (NASD Provides Guidance on Supervisory Responsibilities) (June 1999) (stating that this analysis will enable the member to design a supervisory system that is current and appropriately tailored to its specific attributes and structure). *See also* FINRA Regulatory Notice 14–10 (SEC Approves New Supervision Rules) (Mar. 2014), at 17 n.4 (discussing NASD Notice to Members 99–45).

[302] *See* FINRA Response Letter 2 at 18. We note that the proposed rule does contain a provision—modeled on an analogous provision in the SEC Pay-to-Play Rule—allowing member firms to apply to FINRA for an exemption, conditional or

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C. Comments Requesting Clarification of Terms and Provisions in the Proposal

Commenters asked for clarification of certain defined terms and provisions in the proposed rule, including clarification with respect to: The term "instrumentality" as it is used in the definition of "government entity;" [303] the definition of "covered associate" and the positions that would qualify someone as a covered "official;" [304] whether a "contribution" is also a "payment;" [305] and the factors by which contributions to a PAC would trigger the proposed anti-circumvention rule.[306] In response to these comments, FINRA generally acknowledges, as did the commenters, that these terms are defined in the SEC Pay-to-Play Rule and that FINRA modeled the definitions in its proposal on those in the SEC Pay-to-Play Rule.[307]

The Commission believes that FINRA's definition of "covered associate" in proposed Rule 2030(g) is functionally identical to the definition of the same term in the SEC Pay-to-Play Rule.[308] The definition brings within the ambit of the rule—and its two-year "time-out"—only those contributions made by employees of a member firm who, by virtue of their position or responsibilities, are best positioned to engage in pay-to-play activities as placement agents. It includes "[a]ny general partner, managing member or executive officer of a covered member," any "associated person of a covered member who engages in distribution or solicitation activities with a government entity for such covered member," any associated person who supervises such an employee, and any "political action committee controlled by a covered member or a covered associate." FINRA's rule also adopts the Commission's definition of "executive officer," which was designed to tailor the trigger for the time-out to those officers whose position is most likely to incentivize them to engage in solicitation or distribution activities—and thus most likely to incentivize them to engage in pay-to-play.[309]

FINRA's definition of "official" also tracks the Commission's definition of that same term in the SEC Pay-to-Play Rule and, therefore, limits the rule so that a time-out is triggered only by contributions to certain officials.[310] Under FINRA's proposed rule, the time-out for a placement agent is not triggered by a contribution to every public official running for office; it is triggered only by contributions to a person "who was, at the time of the contribution, an incumbent, candidate or successful candidate for elective office of a government entity, if the office . . . [i]s directly or indirectly responsible for, or can influence the outcome of, the hiring of an investment adviser by a government entity" or a person with authority to appoint someone whose office had the hiring responsibility.[311] FINRA's definition, like the Commission's, is flexible enough to accommodate the myriad State and local political structures while still limiting the reach of the rule to those officials who are responsible for or have authority to appoint any person who is responsible for or can influence the outcome of the hiring of an investment adviser by a government entity.[312]

Additionally, FINRA's definitions of "contribution" and "payment" are functionally identical to those same definitions in the SEC Pay-to-Play Rule.[313] We note that under FINRA's rule, the time-out is *not* triggered by direct contributions to political parties. Therefore, a member firm will not violate the time-out if it receives compensation for solicitation and distribution activities in the wake of contributions that it or its covered associates make to a political party. Instead, FINRA's proposed rule only precludes a covered member from soliciting or coordinating payments to a political party of a State or locality of a government entity with which the covered member is engaging in distribution or solicitation activities on behalf of an investment adviser.[314] FINRA notes in response to a commenter's request for clarification as to whether each and every "contribution" (as defined in proposed FINRA Rule 2030(g)(1)) is, by definition, also a "payment" (as defined in proposed FINRA Rule 2030(g)(9)), that the definition of "payment" is similar to the definition of "contribution," but is broader in the sense that it does not include limitations on the purposes for which such money is given (*e.g.*, it does not have to be made for the purpose of influencing an election).[315]

The Commission believes that FINRA's definitions, which mirror or are functionally equivalent to similar definitions in the SEC's Pay-to-Play Rule, will help to achieve the objectives of the SEC Pay-to-Play Rule and, as described above, the requirements governing the rules of a registered national securities association.[316] The Commission believes that it is appropriate and consistent with the Act for FINRA to encompass in its rule the same definitions and discussion regarding its pay-to-play rules as the Commission did in adopting the SEC Pay-to-Play Rule. The Commission emphasizes that FINRA has committed to working with the industry and the Commission to address interpretive questions and provide additional guidance as needed.[317]

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unconditional, from the proposed rule's two-year "time-out," and enumerates factors for FINRA to consider in deciding whether to grant such an exemption. *See* Proposed Rule 2030(f).

[303] *See* CAI Letter 1.

[304] *See* NAIFA Letter.

[305] *See* CAI Letter 1.

[306] *See* NAIFA Letter.

[307] *See* FINRA Response Letter 2 at 17, 18.

[308] *Compare* Proposed Rule 2030(g)(2), *with* 17 CFR 275.206(4)–5(f)(2).

[309] At least one commenter points out that some entities have precluded all employees from making contributions as a result of the Commission's pay-to-play rule and that FINRA's rule will have the same effect. *See* FSI Letter 2. However, under FINRA's rule (and the SEC Pay-to-Play Rule), only certain employees' contributions will trigger the time-out and the rules on their face do not cover contributions by *all* employees. *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 40131–32.

[310] *Compare* Proposed Rule 2030(g)(8), *with* 17 CFR 275.206(4)–5(f)(6).

[311] *See supra* note 310.

[312] If FINRA were to define "official" by reference to a particular title, such as "Comptroller," the definition would be both over- and under-inclusive. Some officials who have hiring responsibility for investment advisers do not hold the title of "Comptroller," and some officials with the title of "Comptroller" do not have hiring responsibility for investment advisers. Because we understand FINRA's definition to track the definition that we adopted in the SEC Pay-to-Play Rule, we note that it is the scope of authority of the office, not *de facto* influence, that determines whether a contribution will trigger the time-out. *See* SEC Pay-to-Play Adopting Release, 75 FR at 41029.

[313] *Compare* Proposed Rules 2030(g)(8)–(9), *with* 17 CFR 275.206(4)–5(f)(1), 206(4)–5(f)(7).

[314] *See* Proposed Rule 2030(b). This aspect of the rule serves an anti-circumvention function, along with proposed Rule 2030(e), which makes it a violation of the rule "for any covered member or any of its covered associates to do anything indirectly that, if done directly, would result in a violation of this Rule." As FINRA notes, Rule 2030(e) precludes only intentional efforts to circumvent the time-out and a covered member would not violate the rule's prohibition on the receipt of compensation unless there is a showing that the covered member intended to evade the time-out. Thus, a contribution to a PAC—other than a PAC controlled by the covered member, which would be a "covered associate" for purposes of the time-out—would not trigger the time-out and the receipt of compensation in the wake of that contribution would not violate the rule unless it can be shown that the covered member or covered associate who made the contribution intended to circumvent the time-out provision. This provision, which is analogous to a provision in the Commission's Pay-to-Play Rule, precludes a member or its covered associates from, for example, funneling contributions or payments through third parties, such as attorneys, family members, or friends, to complete a pay-to-play arrangement without triggering the time-out.

[315] *See* FINRA Response Letter 2 at 17.

[316] *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41042–44.

[317] There are several ways for industry members to obtain guidance from FINRA about the

D. Comments Regarding the Books and Records Requirements

One commenter claims that not all payments to political parties or PACs should have to be maintained under the books and records requirements of proposed Rule 4580.[318] In response, FINRA states that it has determined to retain the recordkeeping requirements as proposed in the Notice.[319] FINRA notes that, as discussed in the Notice, payments to political parties or PACs can be a means for a covered member or covered associate to funnel contributions to a government official without directly contributing.[320] FINRA states that it proposed requiring a covered member to maintain a record of all payments to political parties or PACs because such records would assist FINRA in identifying situations that might suggest an intent to circumvent the rule.[321]

The Commission acknowledges the comment, but agrees, as noted by FINRA, that payments to political parties or PACs can be a means for a covered member or covered associate to contribute indirectly to a government official in contravention of the proposed rule. The Commission also agrees that requiring FINRA members to maintain a record of all payments to political parties or PACs would assist FINRA in identifying situations that might suggest an intent to violate proposed Rules 2030(b) and 2030(e).[322] The Commission therefore believes that it is appropriate and consistent with the Act for FINRA to require its members to keep records of all such payments to assist FINRA in carrying out its regulatory responsibilities to enforce compliance with the Act and with FINRA's rules.[323]

E. Additional Comments

Certain commenters also suggested that FINRA should include more stringent requirements in its proposed rule.[324] Both commenters suggested that FINRA expand the applicability of its proposed rules to include state-registered investment advisers.[325] In response, FINRA explains that to remain consistent with the SEC Pay-to-Play Rule, FINRA has determined not to expand the scope of the proposed rule as suggested by commenters to include state-registered investment advisers.[326]

The Commission acknowledges this comment but believes that it is appropriate for FINRA to determine to provide for the same scope of its pay-to-play rule as that of the SEC Pay-to-Play Rule. As FINRA notes, the Commission previously declined to make a similar change to the SEC Pay-to-Play Rule stating, among other things, that it was the Commission's understanding that few of these smaller state-registered firms manage public pension plans or other similar funds.[327]

These same commenters suggest that FINRA include a mandatory disgorgement provision for violations of its proposed rule.[328] In response, FINRA explains that it determined not to include a disgorgement requirement in its proposal because it has existing authority to require disgorgement of fees in enforcement actions.[329] The Commission believes that it is appropriate and consistent with the Act for FINRA not to separately require mandatory disgorgement for violations of its proposed rules.

Finally, one of these commenters suggests that the current two-year cooling-off period in the proposal should be at least four years.[330] In response, FINRA states that it believes a two-year time-out from the date of a contribution is sufficient to discourage covered members from participating in pay-to-play practices by requiring a cooling-off period during which the effects of a *quid pro quo* political contribution on the selection process can be expected to dissipate.[331] In addition, FINRA explains that the proposed two-year time-out is consistent with the time-out period in the SEC's Pay-to-Play Rule. The Commission believes that it is appropriate and consistent with the Act for FINRA to determine that a two-year time-out is sufficient to support the objective of the rule to deter pay-to-play activity among its covered members. The Commission notes that the same time period applies in the SEC's Pay-to-Play Rule.

The Commission recognizes these commenters suggest that the rule could have a broader scope. The Commission, however, must evaluate the proposed rule before it and approve a proposed rule if it finds that the proposed rule is consistent with the requirements of the Act and the applicable rules and regulations thereunder. As discussed above, because the rule is consistent with the Act, the Commission is required to approve the FINRA rule.

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application of its rules. Such guidance may include FINRA's publication of Notices to Members and Regulatory Notices, as well as interpretative and exemptive letters. Although FINRA can address interpretive questions with respect to its own rules, for its member firms to satisfy the "regulated person" definition in the SEC Pay-to-Play Rule, the Commission must find that FINRA's pay-to-play rule (i) imposes substantially equivalent or more stringent restrictions on member firms than the SEC Pay-to-Play Rule imposes on investment advisers and (ii) that such rule is consistent with the objectives of the SEC Pay-to-Play Rule. *See supra* note 22 (discussing the Commission's notice of stringency findings dated August 25, 2016). Given the stringency requirements of the SEC Pay-to-Play Rule, we expect our staff to work closely with FINRA regarding interpretive questions about the application and scope of the provisions and terms used in FINRA's rule to the extent those interpretations do not otherwise require FINRA to file a proposed rule change with the Commission pursuant to Section 19(b) of the Act and the rules and regulations thereunder.

[318] *See* CAI Letter 1.

[319] *See* FINRA Response Letter 2 at 20–21.

[320] *See id.* As FINRA explains in the Notice, a covered associate would include a PAC controlled by the covered member or any of its associates. FINRA states that it would consider a covered member or its covered associates to have "control" over a PAC if the covered member or covered associate has the ability to direct or cause the direction of governance or operations of the PAC. *See* Notice, 80 FR at 81653, 81660 (noting that this position is consistent with the position taken by the Commission in connection with the SEC Pay-to-Play Rule) (citing SEC Pay-to-Play Adopting Release, 75 FR at 41032).

[321] *See* FINRA Response Letter 2 at 20. FINRA states in the Notice that the proposed recordkeeping requirements are intended to allow FINRA to examine for compliance with its proposed pay-to-play rule, and the reference to indirect contributions in proposed Rule 4580(a)(4) is intended to include records of contributions or payments a covered member solicits or coordinates another person or PAC to make under proposed Rule 2030(b). *See* Notice, 80 FR at 81663.

[322] We note that proposed Rule 2030(e) would require a showing of intent to circumvent the rule for such persons to trigger the two-year "time-out." *See* Notice, 80 FR at 81654. *See also* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41044 n.340 (explaining that like MSRB Rule G–37(d), SEC Pay-to-Play Rule 206(4)–5(d) also "requires a showing of intent to circumvent the rule for such persons to trigger the time out") (citing *Blount,* 61 F.3d at 948 ("In short, according to the SEC, the rule restricts such gifts and contributions only when they are intended as end-runs around the direct contribution limitations.")).

[323] Section 15A(b)(2) of the Act requires, among other things, that a registered national securities association, such as FINRA, has the capacity to enforce compliance by its members and persons associated with its members with the provisions of the Act, the rules and regulations thereunder, and the rules of the association. *See* 15 U.S.C. 78*o*–3(b)(2).

[324] *See* NASAA Letter and PIABA Letter.

[325] *See* NASAA Letter and PIABA Letter.

[326] *See* FINRA Response Letter 2 at 10.

[327] *See* Notice, 80 FR at 81652 n.26, 81660 n.98. *See also* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41026, 41060. The Commission also explained in connection with the SEC Pay-to-Play Rule that we do not have regulatory authority to oversee the activities of state-registered advisers through examination and our recordkeeping rules, nor does the Commission have authority over the states to oversee their enforcement of their rules. *See* SEC Pay-to-Play Rule Adopting Release, 75 FR at 41026, 41060.

[328] *See* NASAA Letter and PIABA Letter.

[329] *See* FINRA Response Letter 2 at 19–20.

[330] *See* PIABA Letter.

[331] *See* FINRA Response Letter 2 at 10. As the Commission explained, the two-year "cooling-off period" is not a penalty but, rather, is intended to be a period during which any effects of a *quid pro quo* are expected to dissipate. *See* SEC Pay-to-Play Adopting Release, 75 FR at 41026 n.104.

V. Conclusion

Accordingly, for the reasons discussed above, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to such organization.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[332] that the proposed rule change (SR–FINRA–2015–056) be, and hereby is, approved.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–20888 Filed 8–30–16; 8:45 am]

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[332] 15 U.S.C. 78s(b)(2).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78696; File No. SR–BatsEDGX–2016–50]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 19.6, Series of Options Contracts Open for Trading, To Allow Wednesday Expirations for SPY Options

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on August 25, 2016, Bats EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 19.6, entitled "Series of Options Contracts Open for Trading," related to the Short Term Option Series ("STOS") Program to allow Wednesday expirations for SPY options. The Exchange also proposes to make corresponding changes to Rule 16.1, entitled "Definitions."

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to harmonize the Exchange's rules with the rules governing Short Term Options Series programs of other options exchanges. Specifically, the Exchange proposes to amend Rule 19.6, entitled "Series of Options Contracts Open for Trading," related to the STOS Program to allow Wednesday expirations for SPY options. The Exchange also proposes to make certain corresponding changes to 16.1, entitled "Definitions." The proposed rule change is based on the recent approval of a filing submitted by the BOX Options Exchange LLC ("BOX").[5]

Currently, under the STOS Program, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire ("Short Term Option Series"). The Exchange is now proposing to amend its rule to permit the listing of options expiring on Wednesdays. Specifically, the Exchange is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of options on the SPDR S&P 500 ETF Trust ("SPY") to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire ("Wednesday SPY Expirations").[6] The proposed Wednesday SPY Expiration series will be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detail below. The Exchange notes that having Wednesday expirations is not a novel proposal. Specifically, the Chicago Board Options Exchange, Incorporated ("CBOE") recently received approval to list Wednesday expirations for broad-based indexes.[7]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing it from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange will be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion will not apply with Wednesday SPY Expirations and standard monthly options because they will not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week.

Under the proposed Wednesday SPY Expirations, the Exchange may list up to five consecutive Wednesday SPY Expirations at one time. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is the same listing procedure as Short Term Option Series that expire on Fridays. The Exchange is also proposing to clarify that the five series limit in the current Short Term Option Series Program Rule will not include any Wednesday SPY Expirations.[8] This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations will be the same as those for the current Short Term Option Series.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities and Exchange Act Release No. 78668 (August 24, 2016) (SR–BOX–2016–28).

[6] *See* proposed paragraph (g) of Interpretation and Policy .05 to Rule 19.6.

[7] *See* Securities Exchange Act Release No. 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (SR–CBOE–2015–106).

[8] *See* proposed changes to Interpretation and Policy .05 to Rule 19.6.

Specifically, the Wednesday SPY Expirations will have $0.50 strike intervals.

Currently, for each Short Term Option Expiration Date,[9] the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges.[10] The thirty (30) series restriction shall apply to Wednesday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays. As is the case with current Short Term Option Series, the Wednesday SPY Expiration series will be P.M.-settled. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange is also proposing to amend the definition of Short Term Option Series contained in Exchange Rule 16.1(a)(57) to make clear that STOS includes Wednesday expirations and to conform to BOX Rule 100(a)(64). Specifically, the Exchange is amending the definition to expand Short Term Option Series to those listed on any Tuesday or Wednesday and that expire on the Wednesday of the next business week. If a Tuesday or Wednesday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday or Wednesday.

The Exchange believes that the introduction of Wednesday SPY Expirations will provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry. The proposed rule change is a competitive proposal designed to enable the Exchange to compete equally and fairly with other options exchanges in satisfying high market demand for weekly options and continuing strong customer demand to use STOS to execute hedging and trading strategies.

2. Statutory Basis

The rule changes proposed herein are consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[11] Specifically, the proposed change is consistent with Section 6(b)(5) of the Act,[12] because it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, with respect to intermarket competition, the Exchange believes the proposal is pro-competitive and will allow the Exchange to compete more effectively with BOX, which has already adopted changes to its STOS programs that are substantially identical to the changes proposed by this filing.[14] In addition to BOX, the Exchange expects that other options exchanges will file similar proposals to adopt the changes in order to provide Wednesday SPY Expirations.

The Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner as existing Short Term Option Series. The Exchange believes that the proposal will result in additional investment options and opportunities to achieve the investment objectives of market participants seeking efficient trading and hedging vehicles, to the benefit of investors, market participants, and the marketplace in general.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16]

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[9] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* Interpretation and Policy .05 to Rule 19.6.

[10] *See* current paragraph (a) of Interpretation and Policy .05 to Rule 19.6.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] *See supra* note 5.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[17] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[18] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[19] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsEDGX–2016–50 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsEDGX–2016–50. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–50 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20963 Filed 8–30–16; 8:45 am]

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[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] *See supra* note 5.

[19] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78695; File No. SR–NASDAQ–2016–122]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Short Term Option Series Program

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 25, 2016, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the rules of the NASDAQ Options Market LLC ("NOM") to expand the Short Term Option Series Program to allow Wednesday expirations for SPY options.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NOM Rules at Chapter I, Section 1(a)(59) and Chapter IV, Section 6 at Commentary .07 to expand the Short Term Option Series Program to permit the listing and trading of options with Wednesday expirations.

Currently, under the Short Term Option Series Program, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire ("Short Term Option Series"). The Exchange is now proposing to amend its rule to permit the listing of options expiring on Wednesdays. Specifically, the Exchange is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of options on the SPDR S&P 500 ETF Trust (SPY) to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire ("Wednesday SPY Expirations").[3] The proposed Wednesday SPY Expiration series will be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detail below. The Exchange notes that having Wednesday expirations is not a novel proposal. Specifically, BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[4]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing the Exchange from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange will be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion will not apply with Wednesday SPY Expirations and standard monthly options because they will not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week.

Under the proposed Wednesday SPY Expirations, the Exchange may list up to five consecutive Wednesday SPY Expirations at one time. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is the same listing procedure as Short Term Option Series that expire on Fridays. This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations will be the same as those for the current Short Term Option Series. Specifically, the Wednesday SPY Expirations will have $0.50 strike intervals.

Currently, for each Short Term Option Expiration Date,[5] the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges.[6] The thirty (30) series restriction shall apply to Wednesday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays.

The Exchange is also amending the definition of Short Term Option Series to make clear that it includes Wednesday expirations.[7] Specifically, the Exchange is amending the definition to expand Short Term Option Series to those listed on any Tuesday or Wednesday and that expire on the Wednesday of the next business week. If a Tuesday or Wednesday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday or Wednesday. The Exchange believes that the introduction of Wednesday SPY Expirations will provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner. Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in

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[3] *See* NOM Rule Chapter IV, Section 6 at Commentary .07.

[4] *See* Securities Exchange Act Release No. 78668 (SR–BOX–2016–28) (pending publication in the **Federal Register**).

[5] NOM may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* NOM Rule Chapter IV, Section 6 at Commentary .07.

[6] *See* NOM Rule Chapter IV, Section 6 at Commentary .07.

Term Option Series, the Wednesday SPY Expiration series will be P.M.-settled. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

[7] *See* proposed Chapter I, Section 1(a)(59).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series. Also, the Exchange notes that BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that having Wednesday expirations is not a novel proposal, BOX has received approval to list Wednesday expirations for SPY options.[11] The Exchange does not believe the proposal will impose any burden on intra-market competition, as all market participants will be treated in the same manner. Additionally, the Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents the other options exchanges from proposing similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[15] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–122 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–122. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–122 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20962 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78693; File No. SR–Phlx–2016–89]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Short Term Option Series Program

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

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[10] *See* supra, note 4.

[11] *See* supra, note 4.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* note 4.

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 25, 2016, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to expand the Short Term Option Series Program to allow Wednesday expirations for SPY options.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Phlx Rules 1000(44) and Rule 1012 at Commentary .11 to expand the Short Term Option Series Program to permit the listing and trading of options with Wednesday expirations.

Currently, under the Short Term Option Series Program, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire ("Short Term Option Series"). The Exchange is now proposing to amend its rule to permit the listing of options expiring on Wednesdays. Specifically, the Exchange is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of options on the SPDR S&P 500 ETF Trust (SPY) to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire ("Wednesday SPY Expirations").[3] The proposed Wednesday SPY Expiration series will be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detail below. The Exchange notes that having Wednesday expirations is not a novel proposal. Specifically, BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[4]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing the Exchange from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange will be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion will not apply with Wednesday SPY Expirations and standard monthly options because they will not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week.

Under the proposed Wednesday SPY Expirations, the Exchange may list up to five consecutive Wednesday SPY Expirations at one time. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is the same listing procedure as Short Term Option Series that expire on Fridays. This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations will be the same as those for the current Short Term Option Series. Specifically, the Wednesday SPY Expirations will have $0.50 strike intervals.

Currently, for each Short Term Option Expiration Date,[5] the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges.[6] The thirty (30) series restriction shall apply to Wednesday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays.

As is the case with current Short Term Option Series, the Wednesday SPY Expiration series will be P.M.-settled. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange is also amending the definition of Short Term Option Series to make clear that it includes Wednesday expirations.[7] Specifically, the Exchange is amending the definition to expand Short Term Option Series to those listed on any Tuesday or Wednesday and that expire on the Wednesday of the next business week. If a Tuesday or Wednesday is not a business day, the series may be opened

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Phlx Rule 1012 at Commentary .11.

[4] *See* Securities Exchange Act Release No. 78668 (SR–BOX–2016–28) (pending publication in the **Federal Register**).

[5] Phlx may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five consecutive Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* Phlx Rule 1012 at Commentary .11.

[6] *See* Phlx Rule 1012 at Commentary .11.

[7] *See* proposed Rule 1000(44).

(or shall expire) on the first business day immediately prior to that Tuesday or Wednesday. The Exchange believes that the introduction of Wednesday SPY Expirations will provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner. Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series. Also, the Exchange notes that BOX Options Exchange LLC ("BOX") recently received approval to list Wednesday expirations for SPY options.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that having Wednesday expirations is not a novel proposal, BOX has received approval to list Wednesday expirations for SPY options.[11] The Exchange does not believe the proposal will impose any burden on intra-market competition, as all market participants will be treated in the same manner. Additionally, the Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents the other options exchanges from proposing similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[15] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–89 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–89. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–89 and should be submitted on or before September 21, 2016.

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[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See* supra, note 4.

[11] *See* supra, note 4.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* note 4.

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20960 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78681; File No. SR–MIAX–2016–28]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

August 25, 2016.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 11, 2016, Miami International Securities Exchange LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the "Fee Schedule").

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 1)b) of the Fee Schedule, Marketing Fee, to add to the list of symbols for which the Exchange assesses a $0.12 per contract Posted Liquidity Marketing Fee. In addition to the current symbols listed in Section 1)b), the Exchange is proposing to assess the Posted Liquidity Marketing Fee for contracts executed in DIA, FB, GDX, SLV, USO, UVXY, and VXX. The Exchange also proposes to assess the applicable per contract non-Market Maker transaction fees for executions in these new symbols, as described more fully below.

A Marketing Fee is assessed on certain transactions of all Market Makers.[3] Currently, Section 1) b) of the Fee Schedule provides that the Exchange will assess:

(i) A Marketing Fee to all Market Makers for contracts, including mini options, they execute in their assigned classes when the contra-party to the execution is a Priority Customer. MIAX will not assess a Marketing Fee to Market Makers for contracts executed as a PRIME Agency Order, Contra-side Order, Qualified Contingent Cross Order, PRIME Participating Quote or Order, or a PRIME AOC Response in the PRIME Auction, unless it executes against an unrelated order.

(ii) an additional $0.12 per contract Posted Liquidity Marketing Fee to all Market Makers for any standard options overlying EEM, GLD, IWM, QQQ, and SPY that Market Makers execute in their assigned class when the contra-party to the execution is a Priority Customer and the Priority Customer order was posted on the MIAX Book at the time of the execution. MIAX will not assess the additional Posted Liquidity Marketing Fee to Market Makers for contracts executed as a PRIME Agency Order, Contra-side Order, Qualified Contingent Cross Order, or a PRIME AOC Response or PRIME Participating Quote or Order in the PRIME Auction. MIAX will also not assess the additional Posted Liquidity Marketing Fee to Market Makers for contracts executed pursuant to a Liquidity Refresh Pause, route timer, or during the Opening Process. This Posted Liquidity Marketing Fee is in addition to the current Marketing Fee of $0.25 per contract for standard options overlying these enumerated symbols that Market Makers execute in their assigned class when the contra-party to the execution is a Priority Customer.[4]

Funds collected via the Marketing Fee, including the additional $0.12 per contract Posted Liquidity Marketing Fee, are put into "pools" controlled by Primary Lead Market Makers ("PLMMs")[5] and Lead Market Makers ("LMMs").[6] So for example, the $0.12 per contract Posted Liquidity Marketing Fee goes into the broader Marketing Fee pool for the Directed LMM or the PLMM in EEM, GLD, IWM, QQQ or SPY, as applicable. The PLMM or LMM controlling a certain pool of funds can then determine the Electronic Exchange Member(s) ("EEM")[7] to which the funds should be directed in order to encourage such EEM(s) to send orders to the Exchange. In accordance with Exchange Rule 514, an EEM can designate an order ("Directed Order") to a specific LMM.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* MIAX Fee Schedule, Section 1)b), entitled "Marketing Fee" for more detail regarding the Marketing Fee.

[4] *See* Securities Exchange Act Release No. 73848 (December 16, 2014), 79 FR 76421 (December 22, 2014) (SR–MIAX–2014–62) (Notice of Filing and Immediate Effectiveness of MIAX Posted Liquidity Marketing Fee with respect to EEM, GLD, IWM, QQQ and SPY).

[5] The term "Primary Lead Market Maker" means a Lead Market Maker appointed by the Exchange to act as the Primary Lead Market Maker for the purpose of making markets in securities traded on the Exchange. The Primary Lead Market Maker is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Primary Lead Market Makers. *See* Exchange Rule 100.

[6] The term "Lead Market Maker" means a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Lead Market Makers. When a Lead Market Maker is appointed to act in the capacity of a Primary Lead Market Maker, the additional rights and responsibilities of a Primary Lead Market Maker specified in Chapter VI of these Rules will apply. *See* Exchange Rule 100.

The purpose of the Posted Liquidity Marketing Fee is to further encourage Members to post additional Priority Customer orders on the Exchange's Book in the enumerated high volume symbols. Increased Priority Customer orders on the Exchange's Book in these symbols provides for greater liquidity, which benefits all market participants on the Exchange. The Exchange now proposes to add to the following high volume symbols to its Posted Liquidity Marketing Fee program: DIA, FB, GDX, SLV, USO, UVXY, and VXX,[8] as reflected in the proposed amendments to Section (1)(b) and Footnote 15 of the Fee Schedule. The practice of encouraging increased retail customer order flow in order to attract professional liquidity providers (Market Makers) is, and has been, commonly applied in the options markets. As such, marketing fee programs[9] and posting incentive programs[10] are based on attracting public customer order flow. Additional incentives intended to increase order flow in high volume symbols are, and have been, commonly offered in the options markets.[11] The proposed Posted Liquidity Marketing Fee with respect to high volume symbols DIA, FB, GDX, SLV, USO, UVXY, and VXX similarly is intended to attract Priority Customer order flow, which will increase liquidity, thereby providing greater trading opportunities and tighter spreads for other market participants and causing a corresponding increase in order flow from such other market participants. Increasing the number of orders sent to the Exchange will in turn provide tighter and more liquid markets, and therefore attract more business overall.

The Exchange also proposes to adopt the same additional $0.50 per contract transaction fee for options overlying DIA, FB, GDX, SLV, USO, UVXY, and VXX executed by non-MIAX Market Makers as currently applies to options overlying EEM, GLD, IWM, QQQ, and SPY executed by non-MIAX Market Makers as set forth in footnote 8, Section (1)(a)(ii) of the Fee Schedule.[12] The purpose of the proposed fee change is to assess the transaction fee for non-MIAX Market Makers in the new symbols (DIA, FB, GDX, SLV, USO, UVXY, and VXX) that are being added to the Exchange's Posted Liquidity Marketing Fee, in the same manner as the current symbols that are included in each fee.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act[13] in general, and in particular, furthers the objectives of Section 6(b)(4) of the Act,[14] in that it is an equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities, and 6(b)(5) of the Act,[15] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed changes are designed to incentivize order flow providers to post additional Priority Customer orders in DIA, FB, GDX, SLV, USO, UVXY, and VXX options on the Exchange's Book. The proposed marketing fee rate is reasonable in that although it may result in a marketing fee that is slightly higher than similar marketing fee programs, it is still in the range of marketing fee programs on other competing exchanges which charge lower marketing fees for Penny Pilot options classes versus non-Penny Pilot options classes.[16] The proposed marketing fee is fair, equitable, and not unreasonably discriminatory because it will apply equally to all Market Makers that execute against Priority Customer orders in DIA, FB, GDX, SLV, USO, UVXY, and VXX options posted on the Exchange's Book. All similarly situated Market Makers that execute against Priority Customer orders in DIA, FB, GDX, SLV, USO, UVXY, and VXX options that are posted to the Exchange's Book are subject to the same marketing fee, and access to the Exchange is offered on terms that are not unfairly discriminatory. In addition, the proposal is equitable and not unfairly discriminatory because, while only posted Priority Customer order flow qualifies for the additional marketing fee, an increase in Priority Customer orders posted to the Exchange's Book will bring greater volume and liquidity as market participants compete to trade with the additional Priority Customer order flow, which benefits all market participants by providing more trading opportunities and tighter spreads. Market participants want to trade with Priority Customer order flow. To the extent the posting of Priority Customer orders on the Exchange's Book is increased by the proposal, market participants will increasingly compete for the opportunity to trade on the Exchange, including sending more orders and providing narrower and larger sized quotations in their effort to trade with such Priority Customer order flow. The resulting increased volume and liquidity will benefit non-Market Makers that do not pay the proposed fee and do not qualify for the marketing fee program at all, by providing more trading opportunities and tighter spreads as market participants increasingly compete by sending more orders and providing narrower and larger sized quotations in the effort to trade with such Priority Customer order flow. In addition, the proposed change is equitable and not unfairly discriminatory because it is designed to allow LMMs to encourage greater order flow to be sent to the Exchange. The Exchange believes it is equitable to assess marketing fees on Market Makers and not non-Market Makers because the benefits of the marketing fee program flow to PLMM and Directed LMMs that can use the marketing fee funds to attract additional flow to the Exchange, which benefits Market Makers. An LMM could amass a greater pool of funds to use to incentivize order flow providers to send order flow to the Exchange. This increased order flow would benefit all market participants on the Exchange as well.

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[7] The term "Electronic Exchange Member" means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed "members" under the Act. *See* Exchange Rule 100.

[8] DIA, FB, GDX, SLV, USO, UVXY, and VXX had among the highest MIAX volume by class as reported by the Options Clearing Corporation ("OCC") for June 2016. *See http://www.optionsclearing.com/webapps/volbyclass-reports?reportClass=miax.*

[9] *See* MIAX Fee Schedule, Section (1)(b); Chicago Board Options Exchange, Incorporated ("CBOE") Fees Schedule, p. 4; NYSE Amex Options Fee Schedule, p. 7.

[10] *See* NYSE Arca, Inc. ("Arca") Options Fees and Charges Schedule, page 5.

[11] *See* International Securities Exchange, LLC ("ISE") Schedule of Fees, p. 6 ; Arca Option Fees and Charges Schedule, p. 5.

[12] *See* Securities Exchange Act Release No. 73850 (December 16, 2014), 79 FR 76424 (December 22, 2014) (SR–MIAX–2014–63) (Notice of Filing and Immediate Effectiveness of MIAX non-Market Maker Transaction Fee with respect to EEM, GLD, IWM, QQQ and SPY).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(1) and (b)(5).

[16] *See* CBOE Fees Schedule, p. 4; NYSE Amex Options Fee Schedule, p. 7.

The Exchange believes that its proposal to assess the additional Posted Liquidity Marketing Fee for transactions in DIA, FB, GDX, SLV, USO, UVXY, and VXX options, and not other options classes, is consistent with other options markets that provide additional incentives to increase order flow in high volume symbols including assessing different marketing fees for Penny options classes as compared to non-Penny options classes.[17] The Exchange believes that establishing different pricing for DIA, FB, GDX, SLV, USO, UVXY, and VXX Penny Pilot options is reasonable, equitable, and not unfairly discriminatory because DIA, FB, GDX, SLV, USO, UVXY, and VXX options are more liquid options[18] as compared to other Penny Pilot options and the Exchange wants to provide incentive for order flow providers to send such orders to MIAX in order to increase trading opportunities and overall volume executed on the Exchange.

Further, the Exchange's proposed transaction fees for non-MIAX Market Makers in DIA, FB, GDX, SLV, USO, UVXY, and VXX are reasonable in order to ensure that the net transaction fees for non-MIAX Market Makers remain higher than Market Makers in a manner that is designed to encourage market participants to become members and register as Market Makers versus otherwise sending orders to the Exchange as a non-MIAX Market Maker in order to avoid a higher transaction fee.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal is designed to encourage an increase in Priority Customer orders in DIA, FB, GDX, SLV, USO, UVXY, and VXX options posted to the Exchange's Book in order to bring greater volume and liquidity, which benefit all market participants by providing more trading opportunities and tighter spreads. An increase in the submission of Priority Customer orders in DIA, FB, GDX, SLV, USO, UVXY, and VXX options on the Exchange's Book should result in an increase in competition for the opportunity to trade on the Exchange by, among other things, sending more orders and providing narrower and larger sized quotations in the effort to trade with such Priority Customer order flow. The resulting increased volume and liquidity will benefit non-Market Makers that do not pay the proposed fee and do not qualify for the marketing fee program at all, by providing more trading opportunities and tighter spreads.

To the extent that there is additional competitive burden on market participants that are not Priority Customers or Market Makers or trading in other symbols, the Exchange believes that this is appropriate because the proposal should encourage Members to direct additional order flow to the Exchange and thus provide additional liquidity that enhances the quality of its markets and increases the volume of contracts traded on the Exchange. The Exchange believes that all of the Exchange's market participants will benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in order flow directed to the Exchange will benefit all market participants and improve competition on the Exchange.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange believes that the proposed rule change reflects this competitive environment because it establishes a fee structure in a manner that encourages market participants to direct their order flow, to provide liquidity, and to attract additional transaction volume to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[19] and Rule 19b–4(f)(2)[20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2016–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2016–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–

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[17] *See* CBOE Fees Schedule, p. 4; NYSE Amex Options Fee Schedule, p. 7; ISE Schedule of Fees, p. 13; NYSE Arca Options Fees and Charges Schedule, p. 5.

[18] *See supra* note 8.

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 240.19b–4(f)(2).

2016–28, and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20894 Filed 8–30–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78679; File No. SR–NYSE–2016–59]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13 To Eliminate Orders With a Sell "Plus" and Buy "Minus" Instruction and Retain Orders With a "Buy Minus Zero Plus" Instruction, and Make Conforming Changes to Rules 104, 107B, 123C and 1004

August 25, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 19, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) amend Rule 13 to eliminate orders with a sell "plus" and buy "minus" instruction and retain orders with a "Buy Minus Zero Plus" instruction, and (2) make conforming changes to Rules 104, 107B, 123C and 1004. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13 to eliminate orders with a sell "plus" and buy "minus" instruction and retain orders with a "Buy Minus Zero Plus" instruction, and make conforming changes to Rules 104, 107B, 123C and 1004. The Exchange proposes to eliminate orders with a sell "plus" and buy "minus" instruction for all securities both to streamline its rules and reduce complexity among its order type offerings.[4]

Because of the technology changes associated with the proposed rule change, the Exchange proposes to announce the implementation date of the elimination of the order types via Trader Update.

Elimination of Sell "Plus" and Buy "Minus" Order Instructions (Rule 13)

The Exchange proposes to eliminate, and thus delete from its rules, sell "plus" and buy "minus" order instructions, as defined in Rule 13(f)(4)(A) and (B), respectively. Rule 13(f)(4)(B) would also be amended to retain a "Buy Minus Zero Plus" instruction.

First, the Exchange proposes to eliminate the sell "plus" order instruction. An order with a sell "plus" instruction is an order that will not trade at a price that is lower than the last sale if the last sale was a "plus" or "zero plus" tick or that is lower than the last sale plus the minimum fractional change in the stock if the last sale was a "minus" or "zero minus" tick, subject to the limit price of an order, if applicable.[5]

To reflect elimination of the sell "plus" order instruction, the Exchange proposes to delete subsection (f)(4)(A) of Rule 13, which defines the sell "plus" instruction, in its entirety. Subsection (4)(B) of Rule 13(f), amended as described below, would become new subsection (4)(A).

Second, the Exchange proposes to eliminate the buy "minus" order instruction defined in Rule 13(f)(4)(B) and retain the "Buy Minus Zero Plus" order. An order with a buy "minus" instruction will not trade at a price that is higher than the last sale if the last sale was a "minus" or "zero minus" tick or that is higher than the last sale minus the minimum fractional change in the stock if the last sale was a "plus" or "zero plus" tick, subject to the limit price of an order, if applicable.[6]

Exchange rules would continue to permit an order with a "Buy Minus Zero Plus" instruction, which is currently a sub-set of the instructions available under Rule 13(f)(4)(B). A Buy Minus Zero Plus order instruction assists member organizations with compliance with the "safe harbor" provisions of Rule 10b–18 under the Act ("Rule 10b–18") for issuer repurchases.[7] One of the four provisions required to meet the safe harbor provision is if the purchase price of a security does not exceed the highest independent bid or the last independent transaction price.[8] Because an order with a Buy Minus Zero Plus instruction will not trade at a price that is higher than the last sale, member organizations can use this instruction to facilitate their compliance with at least one of the conditions of the safe harbor provision of Rule 10b–18.[9]

To reflect elimination of the buy "minus" order instruction and retention of the "Buy Minus Zero Plus" instruction, the Exchange proposes to add "Zero Plus" after "buy minus" in the first sentence of proposed new Rule 13(f)(4)(A), capitalize "buy minus," and delete the phrase "if the last sale was a 'minus' or 'zero minus' tick or that is higher than the last sale minus the minimum fractional change in the stock if the last sale was a "plus" or "zero plus" tick" following "will not trade at a price that is higher than the last sale." As proposed, an order with an instruction to "Buy Minus Zero Plus" would not trade at a price that is higher than the last sale, subject to the limit price of the order, if applicable.

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[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See, e.g.,* Mary Jo White, Chair, Securities and Exchange Commission, Speech at the Sandler O'Neill & Partners, L.P. Global Exchange and Brokerage Conference (June 5, 2014) (available at *www.sec.gov/News/Speech/Detail/Speech/1370542004312#.U5HI-fmwJiw*).

[5] *See* Rule 13(f)(4)(A).

[6] *See* Rule 13(f)(4)(B).

[7] *See* 17 CFR 240.10b–18.

[8] *See* 17 CFR 240.10b–18(b)(3). The other three conditions relate to time of purchases, volume of purchases, and a requirement that only one broker or dealer be involved in such repurchases on a single day.

[9] The Exchange does not represent that an order with a Buy Minus Zero Plus instruction is guaranteed to meet the requirements of the safe harbor provision of Rule 10b–18; rather, this instruction is available to member organizations to facilitate their own compliance with Rule 10b–18.

The remaining subsections of Rule 13(f)(4) would be amended to reflect these proposed changes, as follows.

Current subsection (C) provides that sell "plus" and buy "minus" instructions are available for Limit Orders, Limit-on-Open ("LOO") Orders, Limit-on-Close ("LOC") Orders, and Market-on-Close ("MOC") Orders. Further, the current rule provides that orders with a buy "minus" instruction that are systemically delivered to Exchange systems will be eligible to be automatically executed in accordance with, and to the extent provided by, Rules 1000–1004, consistent with the order's instructions.

Current subsection (C) would become subsection (B) and would be amended to reflect that the "Buy Minus Zero Plus" order instruction would only be available for limit orders. The Exchange would accordingly amend the first sentence of current subsection (C) to:

- Delete "sell 'plus' and";
- add "Zero Plus" after "buy minus" and capitalize "buy minus";
- delete "LOO Orders, LOC Orders, and MOC Orders"; and
- add the word "only" after "Limit Orders".

The second sentence of proposed new subsection (B) would be amended to:

- Add "Zero Plus" after "buy minus" and capitalize "buy minus"; and
- delete the clause "or sell 'plus' ".

Finally, current subsection (D), which provides that odd-lot sized transactions shall not be considered the last sale for purposes of executing sell "plus" or "buy" minus orders would become new subsection (C) of Rule 13(f)(4). Proposed new subsection (C) would be amended to:

Delete the clause "sell 'plus' or" before "buy minus"; and capitalize "buy minus"; and

- add "Zero Plus" after "buy minus".

Conforming Amendments

The Exchange proposes certain conforming amendments to Rules 104, 107B, 123C and 1004 to reflect the elimination of sell "plus" and buy "minus" instruction as described above as follows.

Rule 104

The Exchange proposes to amend Rule 104 (Dealings and Responsibilities of Designated Market Makers ("DMMs")). Specifically, Rule 104(b)(vi) provides that DMM units may not enter certain orders and modifiers including, among others, orders with Sell "Plus"—Buy "Minus" Instructions.

To conform Rule 104, the Exchange proposes to delete "Sell 'Plus'—" and the quotes around the word "Minus" from Rule 104(b)(vi) and add the phrase "Zero Plus" after "Minus" and before "Instructions." As proposed, Rule 104(b)(vi) would provide that DMM units may not enter orders with Buy Minus Zero Plus Instructions.

Rule 107B

The Exchange proposes to amend Rule 107B (Supplemental Liquidity Providers), which sets forth the rules governing Supplemental Liquidity Providers ("SLPs"). An SLP is an Exchange member organization that electronically enters proprietary orders or quotes from off the Floor into the systems and facilities of the Exchange and is obligated, among other things, to maintain a bid or an offer at the NBB or NBO in each assigned security in round lots for at least 10% of the trading day, on average, and for all assigned SLP securities.[10] Rules 107B(g) sets forth how the Exchange calculates whether an SLP is meeting its 10% quoting requirement. Subsection (D)(iii) of Rule 107B(g) provides that tick sensitive orders such as " 'Sell Plus', 'Buy Minus' (see Rule 13) and 'Buy Minus Zero Plus' " will not be counted as credit towards the 10% quoting requirement.

To conform Rule 107B, the Exchange proposes to delete the phrase "Tick sensitive orders (*i.e.,* "Sell Plus" and "Buy Minus" orders (see Rule 13) and" in subsection (D)(iii), add the word "orders" following "Buy Minus Zero Plus," and delete a parenthesis and quotation marks. As amended, Rule 107B(D)(iii) would provide that Buy Minus Zero Plus orders will not be counted as credit towards the 10% quoting requirement.

Rule 123C

The Exchange proposes to amend Rule 123C (The Closing Procedures), which specifies the procedures to be followed at the close of trading on the Exchange.

Rule 123C(4)(a) describes how the Exchange calculates MOC and LOC imbalances, which is intended to provide market participants with a snapshot of the prices at which interest eligible to participate in the closing transaction would be executed in full against each other at the time the data feed is disseminated. Subsection (vi) of Rule 123C(4)(a) provides that tick sensitive MOC and LOC interest and LOC orders priced equal to the last sale can reduce the Buy or Sell Imbalance to bring the imbalance quantity as close to zero as possible. The Rule also provides that the volume of tick sensitive MOC and LOC orders eligible to reduce the imbalance shall not cause the imbalance to change to the other side.

Rule 123C(4)(a)(vi)(A) specifies that, in the event of a Buy Imbalance, only Sell Plus MOC orders, Sell Plus LOC orders priced equal to or below the last sale price, and Sell and Sell Short LOC orders priced equal to the last sale will be included to offset the imbalance, and that Sell Plus MOC and Sell Plus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions.

Rule 123C(4)(a)(vi)(B) specifies that, in the event of a Sell Imbalance, only Buy Minus MOC orders, Buy Minus LOC orders priced equal to or above the last sale price, and Buy LOC orders priced equal to the last sale will be included to offset the imbalance. The Rule also provides that Buy Minus MOC and Buy Minus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions.

To reflect the elimination of orders with a sell "plus" instruction and buy "minus" instructions, *i.e.,* tick-sensitive orders, and the fact that as proposed, Buy Minus Zero Plus orders would not be available for MOC or LOC Orders, the Exchange proposes to amend Rule 123C as follows:

- Amend Rule 123C(4)(a)(vi) to delete the phrase "tick sensitive MOC orders and LOC orders and" before "LOC orders priced equal to the last sale to bring the imbalance quantity as close to zero as possible." The Exchange also proposes to delete the last sentence in Rule 123C(4)(a)(vi), which provides that "[t]he volume of tick sensitive MOC and LOC orders eligible to reduce the imbalance shall not cause the imbalance to change to the other side."
- Amend Rule 123C(4)(a)(vi) (A) to remove references to Sell Plus MOC orders and Sell Plus LOC orders priced equal to or below the last sale price. The Exchange also proposes to delete the last sentence of the subsection (A), which provides that "Sell Plus MOC and Sell Plus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions."
- Amend Rule 123C(4)(a)(vi)(B) to remove references to Buy Minus MOC

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[10] *See* Rule 107B(a).

orders and Buy Minus LOC orders priced equal to or above the last sale price. The Exchange also proposes to delete the last sentence of the subsection (B), which provides that "Buy Minus MOC and Buy Minus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions."

Rule 1004

Finally, the Exchange proposes to amend Rule 1004 (Election of Buy Minus, Sell Plus and Stop Orders), which provides that automatic executions of transactions reported to the Consolidated Tape shall elect, among others, buy minus and sell plus orders electable at the price of such executions. The Rule further provides that any buy minus and sell plus orders so elected shall be automatically executed as market orders pursuant to Exchange rules.

To reflect the elimination of orders with a Sell "Plus" and Buy "Minus" instruction and retention of "Buy Minus Zero Plus" orders, the Exchange proposes to add "Zero Plus" after "buy minus" in Rule 1004, capitalize "buy minus," and delete the phrase "and sell plus" in two places. The Exchange also proposes to capitalize "market orders." As amended, Rule 1004 would allow for the automatic execution of Buy Minus Zero Plus orders electable at the price of such executions.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[11] of the Act, in general, and furthers the objectives of Section 6(b)(5),[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the Exchange believes that eliminating orders with a sell "plus" and buy "minus" instruction removes impediments to and perfects a national market system by simplifying functionality and complexity of its order types. The Exchange believes that eliminating these order types across all securities would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the removal of complex functionality.

The Exchange further believes that deleting corresponding references in Exchange rules to deleted order types also removes impediments to and perfects the mechanism of a free and open market by ensuring that members, regulators and the public can more easily navigate the Exchange's rulebook and better understand the orders types available for trading on the Exchange. Removing obsolete cross references also furthers the goal of transparency and adds clarity to the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but would rather remove complex functionality and obsolete cross-references, thereby reducing confusion and making the Exchange's rules easier to understand and navigate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2016–59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–59. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–59 and should be submitted on or before September 21, 2016.

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[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20892 Filed 8–30–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78676; File No. SR–NSX–2016–07]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rules Regarding Qualification, Registration and Continuing Education for Persons Associated With Equity Trading Permit Holders, To Add Definitions, Amend Definitions, and To Make Technical, Non-Substantive and Conforming Amendments to Rules

August 25, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Exchange Act" or "Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 24, 2016, National Stock Exchange, Inc. ("NSX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing amendments to its rules regarding qualification, registration and continuing education requirements applicable to Equity Trading Permit ("ETP") Holders[3] and Persons Associated with ETP Holders.[4] The Exchange's rule proposal is intended to align its rules with those of other self-regulatory organizations ("SROs") and thus promote consistency within the securities industry. The Exchange is also proposing to amend NSX Rule 1.5, Definitions, and make technical or conforming changes to certain other NSX rules.

The Exchange has designated this rule proposal as a "non-controversial" rule change pursuant to Section 19(b)(3)(A) of the Act[5] and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.[6]

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nsx.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its qualification, registration, and continuing education requirements applicable to ETP Holders and Persons Associated with ETP Holders. The proposed amendments are intended to: (i) Provide transparency and clarity with respect to the Exchange's registration, qualification, and examination requirements; (ii) ensure that all persons engaging in trading on the Exchange or performing supervisory or operational functions are properly registered and subject to the examination and continuing education requirements necessary for their business function; (iii) align the Exchange's qualification, registration and examination rules with those of the Financial Industry Regulatory Authority ("FINRA") and other SROs so as to promote uniform standards across the securities industry; (iv) provide for the Securities Trader registration (Series 57) and Securities Trader Principal registration; and (v) reorganize certain rules, add new definitions of terms, and make other conforming or ministerial, non-substantive amendments designed to enhance the comprehensiveness and clarity of the Exchange's rules. The proposed changes are discussed below.

Amendments to NSX Rule 1.5—Definitions

The Exchange is proposing to amend NSX Rule 1.5 to add new definitions, revise certain definitions in the current rule, and make non-substantive changes to the rule text. The Exchange first proposes to amend the definition of an ETP in NSX Rule 1.5E.(1). As currently defined in the rule, the term ETP ". . . shall refer to an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's trading facilities. An ETP may be issued to a sole proprietor, partnership, corporation, limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange."

Under the Exchange's proposed amendment, the definition of an "ETP" would retain the text that an ETP shall refer to an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's trading facilities. However, the subsequent text in the current rule, which provides that an ETP may be issued to a sole proprietor, partnership, corporation, limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, will be moved to NSX Rule 2.3, entitled "ETP Holder Eligibility," where it is more logically placed given the content of that rule. Additionally, the relocated text will be amended to add a requirement that the prospective ETP Holder must be a member of another national securities exchange or national securities association in order to be eligible to become an ETP Holder of NSX. The Exchange is proposing this amendment because it will not act as the Designated Examining Authority for any ETP

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[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Exchange Rule 1.5E.(1) defines the term "ETP," in relevant part, as ". . . an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's trading facilities. . . ."

[4] Exchange Rule 1.5P.(2) defines "Person Associated with an ETP Holder" as ". . . any partner, officer, director, or branch manager of an ETP Holder (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with an ETP Holder, or any employee of such ETP Holder, except that any person associated with an ETP Holder whose functions are solely clerical or ministerial shall not be included in the meaning of such terms."

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6)(iii).

Holder under Section 17(d) of the Act[7] and Rules 17d–1[8] and 17d–2[9] thereunder. In new NSX Rule 1.5E.(2), the Exchange proposes to add a new definition of ETP Holder as meaning "the Exchange-approved holder of an ETP" in order to clarify that term and add its definition to Rule 1.5.

The Exchange is also proposing to add new definitions for the terms "Person," "Principal," "Principal—Financial and Operations," "Securities Trader," and "Securities Trader Principal." Proposed Rule 1.5P.(1) will define the term "Person" as a natural person, corporation, partnership, limited liability company, association, joint stock company, trustee of a trust fund, or any organized group of persons whether incorporated or not.[10]

The term "Principal" will be defined in proposed Rule 1.5P.(3) as any person actively engaged in the management of the ETP Holder's securities business, including supervision, solicitation, the conduct of the ETP Holder's business, or the training of Authorized Traders[11] and Persons Associated with the ETP Holder for any of these functions. Such persons shall include Sole Proprietors, Officers, Partners and Directors of Corporations. The definition of a "Principal" in the proposed amendment aligns with the definition of Principal in NASD Rule 1021(b), Definition of Principal.[12]

A Principal—Financial and Operations ("FINOP") will be defined in proposed Rule 1.5P.(4) as a Person Associated with an ETP Holder whose responsibilities include final approval and responsibility for the accuracy of financial reports submitted to securities industry regulatory bodies and the final preparation of such reports; supervision of individuals who assist in the preparation of such reports; supervision of and responsibility for individuals who are involved in the maintenance of the ETP Holder's books and records from which such reports are derived; supervision and/or performance of the ETP Holder's responsibilities under all financial responsibility rules under the provisions of the Act; overall supervision of and responsibility for the individuals who are involved in the administration and maintenance of the ETP Holder's back office operations; or any other matter involving the financial and operational management of the ETP Holder.

The Exchange proposes to add the terms Securities Trader and Securities Trader Principal to Exchange Rule 1.5S. Proposed Rule 1.5S.(1) states that the term "Securities Trader" means any person engaged in the purchase or sale of securities or other similar instruments for the account of an ETP Holder with which such person is associated, as an employee or otherwise, and who does not transact any business with the public. Proposed Rule 1.5S.(2) states that the term "Securities Trader Principal" means a person who has become qualified and registered as a Securities Trader and passes the General Securities Principal qualification examination. Each Principal with responsibility over securities trading activity on the Exchange shall become qualified and registered as a Securities Trader Principal. The Exchange's proposed definitions of the Securities Trader and Securities Trader Principal registration categories align with those contained in NASD Rules 1032 and 1022(a)(6)(A), respectively.

The Exchange also proposes to make changes to the numbering and capitalization and other ministerial changes to Rule 1.5 in light of the additions that have been made to the Rule.

Amendments to Chapter II—ETP Holders of the Exchange

The Exchange is proposing to make changes to Chapter II of its rules with respect to the eligibility, obligations and restrictions applicable to ETP Holders; and the qualification, registration and continuing education requirements applicable to Principals of ETP Holders, Authorized Traders, and Persons Associated with an ETP Holder. The proposed changes will align the Exchange's rules with those of other SROs and provide ETP Holders, their registered and non-registered personnel, and other market participants with reasonable notice of the requirements established by the Exchange in these subject areas.

Amendments to NSX Rule 2.2, Obligations of ETP Holders and the Exchange

The Exchange proposes to amend NSX Rule 2.2, entitled Obligations of ETP Holders and the Exchange. The current text of the rule will be denoted as paragraph (a) and additional rule text will be added in new paragraphs (b) through (e). Proposed paragraph (b) provides that each ETP Holder shall require each Person Associated with such ETP Holder as defined in NSX Rule 1.5P.(2) to agree: (i) To supply the Exchange with such information as may be specified by the Exchange with respect to such person's relationships and dealings with the ETP Holder; (ii) to permit the examination by the Exchange of such person's books and records to verify the accuracy of the information so supplied; and (iii) to be regulated by the Exchange and recognize the Exchange's obligation under the Act to enforce compliance with the Exchange's Rules, By-Laws, Interpretations and Policies and the provisions of the Act and the rules and regulations thereunder. The Exchange is proposing these requirements in order to make more explicit in the Exchange's rules the obligation of ETP Holders, and all Persons Associated with the ETP Holder, to comply with Exchange information requests, to permit the examination of any books and records relevant to the subject matter of an Exchange inquiry, and to consent to the regulatory jurisdiction of the Exchange.[13]

Proposed new subparagraph (c)(i) of Rule 2.2 provides that an ETP Holder shall register through the Central Registration Depository System ("CRD System")[14] as a Principal all persons who meet the definition thereof under Rule 1.5P.(3), *i.e.,* persons actively engaged in the management of the ETP Holder's securities business, including supervision, solicitation, the conduct of the ETP Holder's business, or the training of Authorized Traders and Persons Associated with the ETP Holder for any of these functions. Such persons shall include sole proprietors, officers, partners, and directors of corporations.

Further, pursuant to proposed subparagraph (c)(i), a Principal that is responsible for supervising Authorized Traders or any Principal designated as a Chief Compliance Officer on Schedule A of the ETP Holder's Form BD must pass the General Securities Principal qualification examination ("Series 24") and be registered in CRD. Alternatively, proposed Interpretations and Policies provision .02 provides that the Exchange will accept the New York Stock Exchange ("NYSE") Chief Compliance Officer Examination

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[7] 15 U.S.C. 78q(d).

[8] 17 CFR 240.17d–1.

[9] 17 CFR 240.17d–2.

[10] The proposed definition of a "Person" is the same as that contained in NYSE Arca, Inc. Rule 1.1(v) and NYSE Arca Equities Inc. Rule 1.1(oo).

[11] Exchange Rule 1.5A.(2) defines "Authorized Trader" as ". . . a person who may submit orders (or who supervises a routing engine that may automatically submit orders) to the Exchange's trading facilities on behalf of his or her ETP Holder or Sponsored Participant." No changes to that definition are proposed in this rule filing.

[12] NASD Rule 1021(b), and other NASD Rules regarding the qualification, registration and continuing education requirements for registered personnel, as applicable, are part of FINRA's Transitional Rule Book.

[13] *See* 15 U.S.C.78f(c)(3)(C).

[14] The CRD System is operated by FINRA and defined in proposed NSX Rule 2.2(c). ETP Holders are not required to be members of FINRA.

(“NYSE Series 14”) as an alternative examination to qualify as a Principal a registrant who is identified as the Chief Compliance Officer on the ETP Holder’s Form BD. This provision recognizes that potential registrants cannot register with the Exchange as a Principal using the Series 14 qualification through the CRD System. Except as provided in Interpretations and Policies provisions .04, described below, a Principal must pass the General Securities Representative examination (“Series 7 examination”) or an equivalent foreign examination module as a prerequisite to taking the Series 24 examination.

Proposed subparagraphs (c)(ii) and (iii) of Rule 2.2 require each ETP Holder, except a sole proprietorship or a proprietary trading firm with 25 or fewer Authorized Traders (such entity defined as a “Limited Size Proprietary Firm”), to have a minimum of two registered Principals. A Person registered solely as a FINOP, as defined in Rule 1.5P.(4), does not count toward the two-Principal requirement and shall not be qualified to function in a Principal capacity with responsibility over any area of business activity not described in Rule 1.5P.(4).[15]

Proposed subparagraph (c)(iii) states that for purposes of the Rule, the Exchange proposes to define a proprietary firm as an ETP Holder that trades its own capital and conducts all of its trading activity using exclusively firm accounts and firm funds; does not have customer accounts; whose traders are owners of, employees of, or contractors of the firm; and is not a FINRA member.[16] The Exchange submits that it is appropriate and consistent with the goal of promoting consistency and uniformity in SRO rules, to allow for an exemption from the two-Principal requirement for those ETP Holders that only engage in proprietary trading and have 25 or fewer Authorized Traders. Accordingly, as proposed, such ETP Holders will be required to maintain one Series 24 Registered Principal.

The Exchange further proposes to include a waiver provision that will permit the Exchange to waive the requirements of this proposed subparagraph in situations that indicate conclusively that only one person associated with an applicant for membership should be required to register as a Principal. The Exchange is proposing this amendment to align Rule 2.2(c)(ii) with NASD Rule 1021(e)(2), which contains the same waiver provision.

The Exchange proposes in paragraph (d) of amended NSX Rule 2.2 to require that ETP Holders designate and register with the Exchange through the CRD System a FINOP, as described in proposed NSX Rule 1.5P.(5). The FINOP will be required by the Exchange to pass the Financial and Operations Principal examination (“Series 27” examination”).[17] The proposed rule will allow a FINOP to be either an employee of the ETP Holder or an independent contractor.

The Exchange is further proposing to adopt NSX Rule 2.2(e), Continuing Education Requirements, describing such requirements for all Registered Persons of ETP Holders. The requirements proposed in Rule 2.2(e) are identical to those in the rules of other SROs. For the purposes of paragraph (e) the term “Registered Person” means any Person registered with the Exchange as a General Securities Representative, Securities Trader, Principal, FINOP, Person Associated with an ETP Holder, Authorized Trader, or Market Maker Authorized Trader pursuant to Exchange Rules.[18] Proposed NSX Rule 2.2(e), which aligns with FINRA Rule 1250, establishes both a “Regulatory Element” (applicable to Principals, Authorized Traders and General Securities Representatives) and a “Firm Element” (applicable to those registered persons that have direct customer contact).

The Exchange submits that its proposed adoption of the uniform securities industry rules regarding continuing education requirements will promote uniformity among SRO rules.[19]

Amendments to NSX Rule 2.2, Interpretations and Policies

The Exchange proposes to amend the Interpretations and Policies of NSX Rule 2.2 to add new provisions and to relocate and amend certain text currently found in the Interpretation and Policies provisions of current NSX Rule 2.4 (Restrictions) as Interpretations and Policies to NSX Rule 2.2. Currently, NSX Rule 2.4 Interpretations and Policies describe the qualification requirements that align with NSX Rule 2.2, as proposed to be amended by this rule filing, and the Exchange believes that relocating these provisions will result in a better organizational structure and greater clarity in its rules. The Exchange also proposes to add to the amended NSX Rule 2.2 Interpretations and Policies new provisions relating to the Securities Trader and Securities Trader Principal categories of registration.[20]

As amended, the NSX Rule 2.2 Interpretations and Policies include the following: In provision .01, the Exchange states that it requires the Series 7 or an equivalent foreign examination module approved by the Exchange in qualifying persons seeking registration as General Securities Representatives. The Exchange is relocating this clause from NSX Rule 2.4 Interpretations and Policies, provision .01(c) and adding the text allowing for an equivalent foreign examination module, which will align the Exchange’s requirements with those of other SROs.[21]

In proposed provision .02, the Exchange states that it will accept the NYSE Series 14 as an alternative qualification to the Series 24 to register as a Principal an individual identified as the Chief Compliance Officer on ETP Holder’s Form BD. Additionally, in order to conform to the rules of other SROs, the Exchange specifies in provision .05 that it uses the Uniform Application for Securities Industry Registration or Transfer (“Form U4”), and the Uniform Termination Notice for Securities Industry Registration (“Form U5”), through the CRD System as part of its procedure for registration of ETP Holder personnel. Form U4 shall be amended by the ETP Holder no later than 30 days after an event that would require an amendment to Form U4.

In proposed provision .06, the substance of which is being relocated from NSX Rule 2.4 Interpretations and Policies .01(b), the Exchange will have the authority to waive the requirement of a proficiency examination in exceptional cases, upon a written request and a showing of good cause by an applicant. Advanced age or physical infirmity will not individually of themselves constitute sufficient grounds to waive a qualification examination. Experience in fields ancillary to the investment banking or securities business may constitute sufficient grounds to waive a qualification examination.[22] The Exchange is further proposing to add Interpretations and Policies provision .07. This proposed provision states that any costs borne by the Exchange with respect to registration and examination may be passed through to the applicable ETP Holder. The Exchange believes this addition is necessary to provide ETP Holders with notice that costs may be assessed by the Exchange to comply with the changes to its registration rules.[23]

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[15] The provisions of the proposed rule align with those of other SROs. *See e.g.,* NASD Rule 1022; Bats BZX Exchange, Inc. (“BZX”) Rule 2.5, Interpretations and Policies .01(d).

[16] The definition of “proprietary trading firm” proposed in subparagraph (c)(iii) is identical to that provided in BZX Rule 2.5, Interpretations and Policies 01(g).

[17] *See* NASD Rule 1022(b), (c).

[18] The proposed definition of “Registered Person” is substantially similar to that contained in FINRA Rule 1250(a)(5).

[19] *See, e.g.,* NYSE Rule 345A; NYSE Arca Equities Rule 2.21; BZX and Bats BZY Exchange, Inc. Rules 2.5, Interpretations and Policies .02.

[20] *See* Securities Exchange Act Release No. 75783 (August 28, 2015), 80 FR 53369 (September 3, 2015) (SR–FINRA–2015–17), Order Approving a Proposed Rule Change To Establish the Securities Trader and Securities Trader Principal Registration Categories.

[21] *See, e.g.,* NASD Rule 1032(a)(2); BZX Rule 2.5, Interpretations and Policies .01(c).

Securities Trader and Securities Trader Principal Registrations

The Exchange is proposing to add Interpretations and Policies provisions .03 and .04 to adopt the Securities Trader and Securities Trader Principal registrations.

In proposed provision .03, the Exchange will require the Securities Trader Qualification Examination ("Series 57") and registration for persons meeting the definition of a Securities Trader as set forth in Rule 1.5S.(1). A person registered as a Securities Trader will not be able to function in any other registration category unless he or she is also qualified in such other registration category. For example, a person registered solely as a Securities Trader would not be able to perform all of the functions of a General Securities Representative (Series 7), unless such person had obtained that registration as well.

Proposed provision .04 would further require that a Principal who will have supervisory responsibility for securities trading activity on the Exchange to become qualified and registered as a Securities Trader Principal. Qualification as a Securities Trader Principal would require the Series 57 examination as a prerequisite to taking the Series 24 examination. A Person who is qualified and registered as a Securities Trader Principal may only have supervisory responsibilities for the trading activity described in NASD Rule 1032(f)(1), unless such person is separately qualified and registered in another appropriate principal registration category. A person who is registered as a General Securities Principal shall not be qualified to supervise the trading activities described in NASD Rule 1032(f)(1), unless such person has also become qualified and registered as a Securities Trader under NASD Rule 1032(f) by passing the Securities Trader qualification examination and becoming registered as a Securities Trader Principal.[24] Adopting the Securities Trader and Securities Trader Principal qualification and registration categories will promote consistency and uniformity within the securities industry.

Amendments to NSX Rule 2.4, Restrictions

The Exchange is proposing amendments to NSX Rule 2.4, Restrictions, that are intended to streamline and clarify the rule requirements. In light of other changes contained in this rule proposal, the text of current NSX Rule 2.4(e) and Interpretations and Policies .01 and .02 has been relocated to NSX Rule 2.2 and the Interpretations and Policies to such rule. In certain areas, the repositioned rule text has been further amended. These changes are proposed to better organize the Exchange's requirements for the qualification, registration and continuing education requirements applicable to registered persons. With respect to the remaining text of NSX Rule 2.4, the Exchange is proposing certain non-substantive amendments designed to enhance the clarity of the rule.

Amendments to NSX Rules 2.5, 2.6, 2.7 and 2.11

The Exchange is proposing certain non-substantive, technical or conforming amendments to NSX Rules 2.5, 2.6, 2.7 and 2.11. Current NSX Rule 2.5, Application Procedures for an ETP Holder or to become an Associated Person of an ETP Holder, provides in paragraph (b) that "[a]pplications for association with an ETP Holder shall be made on Form U4 and such other forms as the Exchange may prescribe, and shall be delivered to the Exchange's Vice President of Regulation or such other officer or employee as designated by the Exchange." In view of the Exchange's proposed amendments to NSX Rule 2.2, the text of paragraph (b) is no longer needed and the Exchange proposes to delete this text and denote paragraph (b) as "Reserved."

Similarly, paragraph (f) currently provides that "[e]xcept where, pursuant to Section 17(d) of the Act, the Exchange has been relieved of its responsibility to review and act upon applications for associated persons of an ETP Holder, the procedure set forth in this Chapter shall govern the processing of any such applications." The Exchange is proposing to delete this provision because it retains the authority and responsibility to review and approve applications for associated persons of ETP Holders, and the proposed amendments to the qualification and registration requirements discussed in this filing make this current rule text inapposite. Moreover, were the Exchange to enter into an agreement with another SRO to review and act upon applications for associated persons of ETP Holders, such an agreement would be subject to a filing with the Commission pursuant to Section 17(d) of the Act. Accordingly, the Exchange proposes to delete the current text and make paragraph (f) "Reserved."

The Exchange is proposing ministerial, non-substantive amendments to NSX Rule 2.6, entitled Revocation of an ETP or an Association with an ETP Holder, NSX Rule 2.7, entitled Voluntary Termination of Rights as an ETP Holder and NSX Rule 2.11, entitled NSX Securities, LLC. NSX Rule 2.6 currently states, in relevant part, that "[i]n connection with any revocation or voluntary termination of an ETP pursuant to Rule 2.7, the ETP shall be cancelled." The Exchange proposes to delete the text referencing a voluntary termination of an ETP from NSX Rule 2.6 and add it to NSX Rule 2.7, where it is more logically placed.

Finally, the Exchange proposes a ministerial amendment to Rule 2.11(a)(2) to remove an obsolete reference to the National Association of Securities Dealers ("NASD") as the unaffiliated SRO having oversight responsibilities for NSX Securities, LLC, the Exchange's outbound order routing facility. The correct reference should be to the Financial Industry Regulatory Authority and the Exchange proposes to amend the rule to denote that fact.

Amendments to Chapter XI—Trading Rules

The Exchange is proposing to make several amendments to Chapter XI, Trading Rules. First, the Exchange proposes to amend Rule 11.6, Obligations of Market Maker Authorized Traders, to align the text of the rule with the Exchange's proposed rule changes regarding the qualification and registration of Persons Associated with

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[22] Proposed provision .06 aligns with NASD Rule 1070(d). The Exchange proposes this provision, in part, to allow for experience in fields ancillary to the investment banking or securities business to potentially constitute sufficient grounds to waive a qualification examination, which is in line with FINRA registration rules. Under current Exchange rules, such experience cannot individually of itself constitute sufficient grounds to waive a qualification examination.

[23] The Exchange is not proposing to add a specific fee to its Fee and Rebate Schedule at this juncture and would make a filing with the Commission pursuant to Section 19(b) of the Act, 15 U.S.C. 78s, prior to implementing any such fee.

[24] Proposed provision .04 aligns with NASD Rule 1022(a)(6)(B).

ETP Holders. The Exchange proposes to amend subparagraph (b)(2) of the rule to add text stating that a person who successfully completes the Series 57 qualification examination will be qualified to be registered as a Market Maker Authorized Trader ("MMAT"). The Exchange proposes to remove the Series 7 qualification for registration as an MMAT. The Exchange further proposes to amend subparagraph (b)(2) to eliminate a provision that would allow the Exchange to waive such qualification requirements if the person applying for MMAT status had served as a dealer-specialist or market maker on a registered national securities exchange or association for at least two consecutive years within three years of the date of application. The Exchange believes that requiring the Series 57 as the qualification for registration as an MMAT and the elimination of the waiver provision currently in NSX Rule 11.6(b)(2) will operate to clarify the requirements necessary to qualify as an MMAT and will further promote consistency and uniformity in the rules regarding registration of Associated Persons.

The Exchange is further proposing amendments to NSX Rule 11.10, Authorized Traders, to add new paragraph (e). As proposed, the new rule text will state that, to be eligible for registration as an Authorized Trader of an ETP Holder, a person must successfully complete the Series 57 examination and any other training and/or certification programs as may be required by the Exchange.

The Exchange believes that the proposed amendments to NSX Rules 11.6 and 11.10 will provide internal consistency within NSX's rules and eliminate a fragmented qualification standard for individuals engaged in trading on the Exchange. Currently under Rule 11.6, an individual is required to pass the Series 7 examination to register as an MMAT. Current Rule 11.10 does not include a similar requirement for an Authorized Trader that will not act as an MMAT. The Exchange proposes to replace the Series 7 qualification with the Series 57 qualification for both Authorized Traders and MMATs, thereby providing a uniform registration requirement.

Additionally, the Exchange proposes to change Rule 11.6(b) to clarify that the Exchange will register an MMAT upon receiving a written application from a Market Maker and subject to the eligibility criteria described in the rule. This change is intended to clarify that the MMAT applicant must meet the eligibility criteria set forth in the Rule before the Exchange will register the MMAT.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act[25] in general, and furthers the objectives of Sections 6(b)(5)[26] and 6(c)(3)(B)[27] in particular, in that the amendments are intended to promote just and equitable principles of trade, foster cooperation, and coordination among the SROs responsible for the qualification, registration, and continuing education requirements for registered securities industry personnel, and in general are designed to protect investors the public interest. In addition, the proposed amendments further the objectives of Section 6(c)(3)(B) of the Act, which provides that it is the Exchange's responsibility to prescribe in its rules the standards of training, experience, and competence for ETP Holders and Persons Associated with ETP Holders; the Exchange has the authority under Section 6(c)(3)(B) to bar an individual from becoming an ETP Holder or a person Associated with an ETP Holder, or condition the individual's status as such, if such person does not meet the standards of training, experience and competence that the Exchange prescribes.

The proposed amendments to NSX Rule 1.5, whereby the Exchange proposes to add new definitions for the terms "ETP Holder," "Person," "Principal," "Principal—Financial and Operational," "Securities Trader," and "Securities Trader Principal," are consistent with the statutory provisions in that they add clarity and context to the Exchange's rules regarding securities industry personnel to whom the proposed amended qualification and registration requirements will apply.

The Exchange's proposed amendments to certain provisions contained in Chapter II of the NSX rules, entitled "ETP Holders of the Exchange," also satisfy the requirements of Sections (6)(b)(5) and 6(c)(3)(B) of the Act in that, among other things, they prescribe the standards of training, experience, and competence for ETP Holders and their Associated Persons. Specifically, the proposed amendments to NSX Rule 2.2(b)(i) through (iii), providing that each ETP Holder shall require its Associated Persons to agree: (i) To supply the Exchange with information as requested; (ii) to permit the examination by the Exchange of the person's books and records; and (iii) to be regulated by the Exchange and recognize the Exchange's obligations to enforce compliance with its rules, by-laws and policies and the provisions of the Act, are consistent with Section 6(b)(5) in that they are designed to establish standards of conduct for proposed Associated Persons. The provisions will operate to promote cooperation and coordination among persons regulating the securities markets, which is one of the objectives of Section 6(b)(5).

Proposed NSX Rule 2.2(c)(i)–(iii) addresses the requirements for ETP Holders to register Principals, and provides an exemption from the two-Principal registration requirement for sole proprietorships and proprietary trading firms, the latter as defined in NSX Rule 2.2(c)(iii). Proposed NSX Rule 2.2(d) contains the requirement for each ETP Holder to register a FINOP. These proposed rule provisions are consistent with the rules of other SROs; their adoption by the Exchange is designed to further enhance cooperation and coordination among those entities responsible for regulating the securities industry, thereby meeting the statutory requirement set forth in Section 6(b)(5).

In proposed NSX Rules 2.2(e)(i) and (ii) the Exchange will adopt the uniform industry rules establishing continuing education requirements for the registered personnel. The proposed revisions will contribute to the consistency of application of continuing education requirements and meet the statutory mandate of Section 6(c)(3)(B) that the Exchange's rules be designed to prescribe standards of training and competence for registered personnel associated with its ETP Holders. The proposed continuing education requirements will contribute to uniform standards across the securities industry and avoid unnecessary duplication or inconsistencies among SRO rules.

The Exchange's proposed amendments to Interpretations and Policies .01 through .07 of NSX Rule 2.2 also meet the requirements of Sections 6(b)(5) and 6(c)(3)(B) pursuant to the Act. These proposed amendments specify that: (i) The Exchange requires the Series 7 or an equivalent foreign examination module in qualifying persons as General Securities Representatives; (ii) the NYSE Series 14 can be used as a qualification for Principals designated as an ETP Holder's Chief Compliance Officer; (iii) those who meet the qualifications of a Securities Trader must pass the Series 57; (iv) any Principal who supervises Securities Trading activity must qualify as a Securities Trader Principal, and only a Principal qualified as a Securities

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[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(c)(3)(B).

Trader Principal may supervise Securities Trading activity; (v) ETP Holders must use the Form U4 and Form U5 for registration and termination of ETP Holder personnel; (vi) the Exchange may grant a waiver of an examination requirement in exceptional cases and upon a showing of good cause; and (vii) the Exchange may pass through the reasonable costs associated with such examinations and qualifications to ETP Holders. All of these proposed amendments to the NSX Rule 2.2 Interpretations and Policies are designed to align the Exchange's rules with the qualification and registration requirements of other SROs and thus are designed to promote uniformity and certainty in the securities industry, which is consistent with the statutory mandate of Section 6(b)(5) of the Act that the rules of the Exchange foster coordination and cooperation among those entities regulating the securities markets.

The Exchange's proposed amendments to NSX Rules 2.5, 2.6, 2.7, and 2.11 are designed as conforming amendments that resulted from the proposed changes to the Exchange's qualification and registration rules, or are ministerial, non-substantive changes designed to correct deficient or obsolete text and promote clarity and consistency in the Exchange's rules. Such amendments are consistent with Section 6(b)(5) of the Act in that, by enhancing the organization and clarity of the Exchange's rules, they operate to promote just and equitable principles of trade.

The Exchange has further proposed amendments Chapter XI, Trading Rules, and specifically to NSX Rules 11.6 and 11.10. The proposed amendments codify the qualification standards for MMATs and for Authorized Traders. The proposed amendments are designed to establish the standard of competence and knowledge required of those categories of registered personnel, which is consistent with the requirements of Section 6(c)(3)(B) of the Act. The adoption of these rule amendments will conform the Exchange's standards those of FINRA and other SROs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed amendments are intended to promote transparency in the Exchange's rules, and consistency with the rules of other SROs with respect to the examination, qualification, and continuing education requirements applicable to ETP Holders and their registered personnel. The Exchange believes in that regard that any burden on competition would be clearly outweighed by the important regulatory goal of ensuring clear and consistent requirements applicable across SROs, avoiding duplication, and mitigating any risk of SROs implementing different standards in these important areas.

Further, the Exchange does not believe that the proposed amendments will affect competition among securities markets since FINRA and exchanges have adopted similar rules with uniform standards for qualification, registration and continuing education requirements.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited or received any comments on the proposed rule change from market participants or others.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) [28] of the Exchange Act and Rule 19b–4(f)(6) thereunder.[29]

At any time within sixty (60) days of the filing of such proposed rule change, the Commission may summarily temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSX–2016–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NSX–2016–07. This file number should be included in the subject line if email is used. To help the Commission process and review comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. eastern time. Copies of such filings will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to file number SR–NSX–2016–07 and should be submitted on or before September 21, 2016.

For the Commission by the Division of Trading and Markets, pursuant to the delegated authority.[30]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20883 Filed 8–30–16; 8:45 am]

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[28] 15 U.S.C. 78(s)(b)(3)(A).

[29] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description of the text of the proposed rule change, at least five business days prior to the date of the filing of the proposed rule change, or such other time as designated by the Commission. The Exchange provided the Commission with the required notice.

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78686; File No. SR–CBOE–2016–062]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Short Term Option Series Program To Allow Wednesday Expirations for SPY Options

August 25, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),[1] and Rule 19b–4 thereunder, [2] notice is hereby given that, on August 24, 2016, Chicago Board Options Exchange, Incorporated (the “Exchange” or “CBOE”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to expand the Short Term Option Series Program to allow Wednesday expirations for SPDR S&P 500 ETF Trust (“SPY”) options. The text of the proposed rule change is available on the Exchange’s Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange’s Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to expand the Short Term Option Series Program outlined in Rule 5.5(d) to allow the listing and trading of SPY options with Wednesday expirations. This is a competitive filing based on a filing submitted by the BOX Options Exchange, LLC (“BOX”), which the Commission recently approved.[5]

Currently, under the Short Term Option Series Program, which was made permanent in 2009,[6] the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire (“Short Term Option Series”). The Exchange is now proposing to amend Rule 5.5(d) to permit the listing of SPY options expiring on Wednesdays. Specifically, CBOE is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of SPY options that expire on any Wednesday of the month that is a business day and is not a Wednesday on which Quarterly Options Series expire (“Wednesday SPY Expirations”).[7] The proposed Wednesday SPY Expiration series would be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detailed below. The Exchange notes that Wednesday expirations are not a novel proposal. Specifically, the U.S. Securities and Exchange Commission (“Commission”) approved a CBOE proposal to list Wednesday expirations for broad-based indexes.[8] Additionally, BOX recently received approval to list Wednesday SPY Expirations.[9]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing CBOE from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange would be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion would not apply with Wednesday SPY Expirations and standard monthly options because they would not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week. The existing restriction that a Short Term Option Series may not expire on the same day that a Quarterly Option Series expires would apply to Wednesday SPY Expirations.

Under the proposal, CBOE may open for trading on any Tuesday or Wednesday that is a business day, series of SPY options that expire at the close of business on each of the next five Wednesdays that are business days and are not Wednesdays on which Quarterly Options Series expire. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is similar to the listing procedures for Short Term Option Series that expire on Fridays. If the Exchange is not open for business on the respective Tuesday or Wednesday, the Wednesday SPY Expiration Opening Date will be the first business day immediately prior to that respective Tuesday or Wednesday. Similarly, if the Exchange is not open for business on a Wednesday, the expiration date for a Wednesday SPY Expiration will be the first business day immediately prior to that Wednesday. This is also similar to the procedures for Short Term Option Series that expire on Fridays.

The Exchange is also proposing to clarify that the five expirations limit in the current Short Term Option Series Program Rule would not include any Wednesday SPY Expirations and vice versa.[10] This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations would be the same as those for the current Short Term Option Series. Specifically, the Wednesday SPY Expirations would have $0.50 strike intervals.[11]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 78668 (August 24, 2016) (order approving SR–BOX–2016–028).

[6] *See* Securities Exchange Act Release No. 59824 (April 27, 2009), 74 FR 20518 (May 4, 2009) (SR–CBOE–2009–018).

[7] *See* proposed amendment to Rule 5.5(d).

[8] *See* Securities Exchange Act Release No. 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (Order approving SR–CBOE–2015–106).

[9] *See* supra note 5.

[10] Specifically, the Exchange proposes to add the following new text to Rule 5.5(d) in relevant places, “Wednesday SPY Expirations (described in the paragraph below) are not included as part of this count [ ]” and “Non-Wednesday SPY Expirations (described in the paragraph above) are not included as part of this count.”

Currently, for each Short Term Option Expiration Date,[12] the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are opened by other securities exchanges under their respective short term option rules; CBOE may list these additional series that are listed by other exchanges.[13] The thirty (30) series restriction would apply to Wednesday SPY Expiration series as well. In addition, the Exchange would be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays.

As is the case with current Short Term Option Series, the Wednesday SPY Expiration series would be P.M.-settled. The Exchange does not believe that any market disruptions would be encountered with the introduction of P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange is also proposing to amend Rule 1.1(bbb), which sets forth the definition of Short Term Option Series. The definition set forth in Rule 1.1(bbb) is redundant to the terms for Short Term Option Series set forth in Rule 5.5. As a result, the Exchange believes that amending Rule 1.1(bbb) by including an internal cross reference to Rule 5.5(d) and by deleting redundant language would result in a less bulky definition and would make the Rulebook more user friendly.

The Exchange is taking this opportunity to amend Rule 5.5(d) with respect to Exchange closures on Fridays that would otherwise be eligible as Short Term Option Expiration Dates. Specifically, the Exchange is cleaning up outdated language that previously tied listings to Fridays in the following business week, *i.e.*, "if the Exchange is not open for business on the Friday of the following business week . . . ." Since Short Term Option Series may be listed out over five consecutive Fridays, the existing language is unnecessarily restrictive. Also, this proposed change harmonizes the Exchange's rule text with existing BOX rule text, *i.e.*, "if the [Exchange] is not open for business on a Friday . . ."

The Exchange proposes to add the new rule text language regarding Wednesday SPY Expirations at the beginning of Rule 5.5(d), before the provisions governing classes, expiration, initial series, additional series, strike interval and delisting. The Exchange believes that placement of Wednesday SPY Expirations at the start of Rule 5.5(d) would make it apparent that the rest of Rule 5.5(d) applies to Wednesday SPY Expirations. To make this point clear, the Exchange proposes to add the sentence, "References to 'Short Term Option Series' below shall be read to include 'Wednesday SPY Expirations,' except where indicated otherwise[ ]" before the Arabic numbered paragraphs set forth in Rule 5.5(d).

The Exchange believes that the introduction of Wednesday SPY Expirations would provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[14] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week would benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner.

In addition to the substantive proposal to permit Wednesday SPY Expirations, the Exchange is proposing to make two technical changes to the text of Rule 5.5(d). One proposed change is grammatical and the other is a cleanup change that would benefit investors because CBOE's Rulebook would have parallel structure and would be more user friendly.

The Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. Finally, the Exchange also represents that it has the necessary systems capacity to support the new options series.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that it currently trades Wednesday expirations for certain broad-based index options. As a result, having Wednesday expirations is not a novel proposal. Additionally, the current rule change is being proposed as a competitive response to a recently approved BOX filing. CBOE believes this proposed rule change is necessary to ensure fair competition among the options exchanges. Also, the Exchange does not believe the proposal would impose any burden on intramarket competition, as all market participants would be treated in the same manner as they are with respect to existing Short Term Option Series. Additionally, the Exchange does not believe the proposal would impose any burden on intermarket competition, as nothing prevents the other options exchanges from proposing similar rules to those that the Exchange is currently proposing.

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[11] This is because SPY options have $1 strike price intervals for non-Short Term Option series. *See* Rule 5.5.08(b). Pursuant to Rule 5.5(d)(5)(ii), strike price intervals for Short Term Option Series may be $0.50 or greater for classes that trade in $1 strike price intervals for non-Short Term Option series. The Exchange is taking this opportunity to harmonize Rule 5.5(d)(5)(ii) with Rule 5.5(d)(5)(i) and (iii) by adding the phrase "or greater." This proposed change is non-substantive.

[12] CBOE may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* Rule 5.5(d).

[13] *See* Rule 5.5(d)(1).

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii) [18] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[19] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–062 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–062. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–062 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20887 Filed 8–30–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78674; File No. SR–NYSEArca–2016–116]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Arca Equities Rule 5.3(i)(3) To Amend the Requirements for the Dissemination of News in Compliance With the Exchange's Immediate Release Policy

August 25, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 ("Act") [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 12, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

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[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] *See supra* note 5.

[20] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Equities Rule 5.3(i)(3) to amend the requirements for the dissemination of news in compliance with the Exchange's immediate release policy. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca Equities Rules 5.3(i)(2) and (3) require a listed company to make immediate public disclosure of all material information concerning its affairs (the "immediate release policy"). NYSE Arca Equities Rule 5.3(i)(3) provides that companies should comply with the immediate release policy by releasing material information "simultaneously to any of the following organizations":

> "(a) the primary business and financial newswire services (Dow Jones and Reuters);
>
> (b) the national services (*e.g.,* Associated Press);
>
> (c) The WALL STREET JOURNAL, NEW YORK TIMES, LOS ANGELES TIMES, SAN FRANCISCO CHRONICLE, and SAN FRANCISCO EXAMINER;
>
> (d) Moody's Investors Service and Standard & Poor's Corporation; and
>
> (e) a company that distributes press releases over private teletype networks may find PR Newswire and Business Wire helpful in gaining news coverage."

The Exchange proposes to amend Rule 5.3(i)(3) to conform it to the immediate release policies of the New York Stock Exchange ("NYSE"), NYSE MKT and Nasdaq.[4] Most significantly, the amended rule will provide that companies can comply with the Exchange's immediate release policy by disseminating the material information by any Regulation FD compliant method or combination of methods. Regulation FD was adopted by the Commission in 2000 in order to curb the selective disclosure of material non-public information by issuers to analysts and institutional investors.[5] Generally, Regulation FD requires that when an issuer discloses material information, it do so publicly. Public disclosure under Regulation FD can be accomplished by filing a Form 8–K with the Commission or through another method of disclosure that is reasonably designed to provide broad, non-exclusionary distribution of the information to the public (*e.g.* press releases, conference calls, press conferences and webcasts, so long as the public is provided adequate notice and granted access).[6] The Exchange now proposes to amend Rule 5.3(i)(3) to provide that companies may comply with the immediate release policy by disseminating the information using any method (or combination of methods) that constitutes compliance with Regulation FD.

Foreign private issuers and issuers registered under the Investment Company Act other than closed end funds are subject to the immediate release policy but they are not required to comply with Regulation FD.[7] Notwithstanding their exemption from Regulation FD, Rule 5.3(i)(3) as amended will allow foreign private issuers and Investment Company Act registrants other than closed end funds to comply with the Exchange's immediate release policy by any method (or combination of methods) that would constitute compliance with Regulation FD for a domestic U.S. issuer.

While the Exchange continues to believe that there are benefits to the market and investors generally if companies issue press releases when disclosing material information, the Exchange nonetheless believes that it is appropriate to harmonize its requirements in this regard with Regulation FD, as well as with Section 202.06 of the NYSE Listed Company Manual, NYSE MKT Company Guide Section 402 and Nasdaq Marketplace Rule 5250(b)(1), thereby eliminating the confusion inherent in having different regimes applied by different listing exchanges and the Commission. The Exchange believes that many companies will continue to issue press releases in relation to material news events, and the proposed amendment includes language that encourages companies to disclose material news via a press release. However, the Exchange also believes that it is appropriate to enable companies to utilize the [sic] flexibility and discretion with respect to the method of disclosure provided by Regulation FD.

The Exchange also proposes to delete from the rule the existing list of methods for disseminating material news and to instead specify in the revised rule that any company disseminating material news by means of a press release should release it to the major news wire services, including, at a minimum, Dow Jones & Company, Inc., Reuters Economic Services and Bloomberg Business News. This revised provision is the same as the press release requirements of the NYSE and, in the Exchange's opinion, it represents a more effective approach to news dissemination than may be the case under some of the approaches permitted under the current rule.

The Exchange proposes to include language in the revised rule specifying that listed companies choosing to comply with the immediate release policy by disseminating information via their Web site or social media must comply with the Commission's guidelines applicable to the use of companies' Web sites or social media for purposes of compliance with Regulation FD.[8]

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[4] *See* Securities Exchange Act Release No. 34–59823 (April 27, 2009); 74 FR 20516 (May 4, 2009) (SR–NYSE–2009–40). *See also* Securities Exchange Act Release No. 46288 (July 31, 2002), 67 FR 51306 (August 7, 2002) (SR–NASD–2002–85). *See also* Securities Exchange Act Release No. 34–75167 (June 12, 2015); 80 FR 34949 (June 18, 2015) (SR–NYSEMKT–2015–40).

[5] *See* Securities Exchange Act Release No. 43154 (August 15, 2000), 65 FR 51716 (August 24, 2000) ("Regulation FD Adopting Release").

[6] *See* Regulation FD Adopting Release at pages 51723–51724.

[7] *See* the definition of an "issuer" subject to Regulation FD as set forth in Section 101(b) thereof: An "issuer" subject to this regulation is one that has a class of securities registered under Section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*), or is required to file reports under Section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78o(d)), including any closed-end investment company (as defined in Section 5(a)(2) of the Investment Company Act of 1940) (15 U.S.C. 80a–5(a)(2)), but not including any other investment company or any foreign government or foreign private issuer, as those terms are defined in Rule 405 under the Securities Act.

[8] *See* Securities Exchange Act Release No. 58288 (August 1, 2008); 73 FR 45862 (August 7, 2008) (Commission Guidance on the Use of Company Web sites). *See also* Securities Exchange Act Release No. 69279 (April 2, 2013) (Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934: Netflix, Inc., and Reed Hastings) (available at *https://www.sec.gov/*

The Exchange also proposes to replace references to the "Securities Qualification Department" and the "Surveillance Department" throughout Rule 5.3 and in Rule 5.5(m) with references to NYSE Regulation, as there are no longer groups within the Exchange with those titles and the relevant work is performed in each case by the staff of NYSE Regulation.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(5)[10] of the Act, in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes the proposed amendment is consistent with the investor protection objectives of the Act in that it harmonizes the Exchange's immediate release policy with the Commission's requirements in Regulation FD. The Exchange believes that the remaining proposed amendments are consistent with Section 6(b)(5) of the Act, as none of them make substantive changes to the Exchange's listing requirements.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed amendment simply harmonizes the Exchange's immediate release policy with the Commission's requirements in Regulation FD. The proposed amendment also harmonizes the method of compliance with the Exchange's immediate release policy with the methods of compliance for the NYSE, NYSE MKT and Nasdaq immediate release policies and makes other non-substantive changes to the Company Guide. Accordingly, there will be no burden on competition because the other markets already have similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)[13] of the Act and Rule 19b–4(f)(6) thereunder.[14]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–116 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–116. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–116 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20881 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

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litigation/investreport/34-69279.pdf). The Exchange will remind listed companies of the Commission's guidelines with respect to the use of Web sites and social media to disseminate material information.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6).

[13] 15 U.S.C. 78s(b)(3)(A)

[14] 17 CFR 240.19b–4(f)(6). In addition, the Commission notes that Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing, or such shorter time as the Commission may designate. The Exchange has satisfied that requirement.

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78692; File No. SR–NYSEMKT–2016–81]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13—Equities To Eliminate Orders With a Sell "Plus" and Buy "Minus" Instruction and Retain Orders With a "Buy Minus Zero Plus" Instruction, and Make Conforming Changes to Rules 104—Equities, 107B—Equities, 123C—Equities and 1004—Equities

August 26, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 19, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13—Equities to eliminate orders with a sell "plus" and buy "minus" instruction and retain orders with a "Buy Minus Zero Plus" instruction, and (2) make conforming changes to Rules 104—Equities, 107B—Equities, 123C—Equities and 1004—Equities. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13—Equities ("Rule 13") to eliminate orders with a sell "plus" and buy "minus" instruction and retain orders with a "Buy Minus Zero Plus" instruction, and make conforming changes to Rules 104—Equities ("Rule 104"), 107B—Equities ("Rule 107B"), 123C—Equities ("Rule 123C") and 1004—Equities ("Rule 1004"). The Exchange proposes to eliminate orders with a sell "plus" and buy "minus" instruction for all securities both to streamline its rules and reduce complexity among its order type offerings.[4]

Because of the technology changes associated with the proposed rule change, the Exchange proposes to announce the implementation date of the elimination of the order types via Trader Update.

Elimination of Sell "Plus" and Buy "Minus" Order Instructions (Rule 13)

The Exchange proposes to eliminate, and thus delete from its rules, sell "plus" and buy "minus" order instructions, as defined in Rule 13(f)(4)(A) and (B), respectively. Rule 13(f)(4)(B) would also be amended to retain a "Buy Minus Zero Plus" instruction.

First, the Exchange proposes to eliminate the sell "plus" order instruction. An order with a sell "plus" instruction is an order that will not trade at a price that is lower than the last sale if the last sale was a "plus" or "zero plus" tick or that is lower than the last sale plus the minimum fractional change in the stock if the last sale was a "minus" or "zero minus" tick, subject to the limit price of an order, if applicable.[5]

To reflect elimination of the sell "plus" order instruction, the Exchange proposes to delete subsection (f)(4)(A) of Rule 13, which defines the sell "plus" instruction, in its entirety. Subsection (4)(B) of Rule 13(f), amended as described below, would become new subsection (4)(A).

Second, the Exchange proposes to eliminate the buy "minus" order instruction defined in Rule 13(f)(4)(B) and retain the "Buy Minus Zero Plus" order. An order with a buy "minus" instruction will not trade at a price that is higher than the last sale if the last sale was a "minus" or "zero minus" tick or that is higher than the last sale minus the minimum fractional change in the stock if the last sale was a "plus" or "zero plus" tick, subject to the limit price of an order, if applicable.[6]

Exchange rules would continue to permit an order with a "Buy Minus Zero Plus" instruction, which is currently a sub-set of the instructions available under Rule 13(f)(4)(B). A Buy Minus Zero Plus order instruction assists member organizations with compliance with the "safe harbor" provisions of Rule 10b–18 under the Act ("Rule 10b–18") for issuer repurchases.[7] One of the four provisions required to meet the safe harbor provision is if the purchase price of a security does not exceed the highest independent bid or the last independent transaction price.[8] Because an order with a Buy Minus Zero Plus instruction will not trade at a price that is higher than the last sale, member organizations can use this instruction to facilitate their compliance with at least one of the conditions of the safe harbor provision of Rule 10b–18.[9]

To reflect elimination of the buy "minus" order instruction and retention of the "Buy Minus Zero Plus" instruction, the Exchange proposes to add "Zero Plus" after "buy minus" in the first sentence of proposed new Rule 13(f)(4)(A), capitalize "buy minus," and delete the phrase "if the last sale was a 'minus' or 'zero minus' tick or that is higher than the last sale minus the minimum fractional change in the stock if the last sale was a "plus" or "zero plus" tick" following "will not trade at a price that is higher than the last sale." As proposed, an order with an instruction to "Buy Minus Zero Plus" would not trade at a price that is higher than the last sale, subject to the limit price of the order, if applicable.

The remaining subsections of Rule 13(f)(4) would be amended to reflect these proposed changes, as follows.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See, e.g.,* Mary Jo White, Chair, Securities and Exchange Commission, Speech at the Sandler O'Neill & Partners, L.P. Global Exchange and Brokerage Conference (June 5, 2014) (available at *www.sec.gov/News/Speech/Detail/Speech/1370542004312#.U5HI-fmwJiw*).

[5] *See* Rule 13(f)(4)(A)—Equities.

[6] *See* Rule 13(f)(4)(B)—Equities.

[7] *See* 17 CFR 240.10b–18.

[8] *See* 17 CFR 240.10b–18(b)(3). The other three conditions relate to time of purchases, volume of purchases, and a requirement that only one broker or dealer be involved in such repurchases on a single day.

[9] The Exchange does not represent that an order with a Buy Minus Zero Plus instruction is guaranteed to meet the requirements of the safe harbor provision of Rule 10b–18; rather, this instruction is available to member organizations to facilitate their own compliance with Rule 10b–18.

Current subsection (C) provides that sell "plus" and buy "minus" instructions are available for Limit Orders, Limit-on-Open ("LOO") Orders, Limit-on-Close ("LOC") Orders, and Market-on-Close ("MOC") Orders. Further, the current rule provides that orders with a buy "minus" instruction that are systemically delivered to Exchange systems will be eligible to be automatically executed in accordance with, and to the extent provided by, Rules 1000–1004—Equities, consistent with the order's instructions.

Current subsection (C) would become subsection (B) and would be amended to reflect that the "Buy Minus Zero Plus" order instruction would only be available for limit orders. The Exchange would accordingly amend the first sentence of current subsection (C) to:

- Delete "sell 'plus' and";
- add "Zero Plus" after "buy minus" and capitalize "buy minus";
- delete "LOO Orders, LOC Orders, and MOC Orders"; and
- add the word "only" after "Limit Orders".

The second sentence of proposed new subsection (B) would be amended to:

- Add "Zero Plus" after "buy minus" and capitalize "buy minus"; and
- delete the clause "or sell 'plus' ".

Finally, current subsection (D), which provides that odd-lot sized transactions shall not be considered the last sale for purposes of executing sell "plus" or "buy" minus orders would become new subsection (C) of Rule 13(f)(4). Proposed new subsection (C) would be amended to:

- Delete the clause "sell 'plus' or" before "buy minus"; and capitalize "buy minus"; and
- add "Zero Plus" after "buy minus".

Conforming Amendments

The Exchange proposes certain conforming amendments to Rules 104, 107B, 123C and 1004 to reflect the elimination of sell "plus" and buy "minus" instruction as described above as follows.

Rule 104

The Exchange proposes to amend Rule 104 (Dealings and Responsibilities of Designated Market Makers ("DMMs")). Specifically, Rule 104(b)(vi) provides that DMM units may not enter certain orders and modifiers including, among others, orders with Sell "Plus"—Buy "Minus" Instructions.

To conform Rule 104, the Exchange proposes to delete "Sell 'Plus'—" and the quotes around the word "Minus" from Rule 104(b)(vi) and add the phrase "Zero Plus" after "Minus" and before "Instructions." As proposed, Rule 104(b)(vi) would provide that DMM units may not enter orders with Buy Minus Zero Plus Instructions.

Rule 107B

The Exchange proposes to amend Rule 107B (Supplemental Liquidity Providers), which sets forth the rules governing Supplemental Liquidity Providers ("SLPs"). An SLP is an Exchange member organization that electronically enters proprietary orders or quotes from off the Floor into the systems and facilities of the Exchange and is obligated, among other things, to maintain a bid or an offer at the NBB or NBO in each assigned security in round lots for at least 5% of the trading day, on average, and for all assigned SLP securities.[10] Rules 107B(g) sets forth how the Exchange calculates whether an SLP is meeting its 5% quoting requirement. Subsection (D)(iii) of Rule 107B(g) provides that tick sensitive orders such as "'Sell Plus', 'Buy Minus' (see Rule 13) and 'Buy Minus Zero Plus'" will not be counted as credit towards the 5% quoting requirement.

To conform Rule 107B, the Exchange proposes to delete the phrase "Tick sensitive orders (*i.e.*, "Sell Plus" and "Buy Minus" orders (see Rule 13) and" in subsection (D)(iii), add the word "orders" following "Buy Minus Zero Plus," and delete a parenthesis and quotation marks. As amended, Rule 107B(D)(iii) would provide that Buy Minus Zero Plus orders will not be counted as credit towards the 10% quoting requirement.

Rule 123C

The Exchange proposes to amend Rule 123C (The Closing Procedures), which specifies the procedures to be followed at the close of trading on the Exchange.

Rule 123C(4)(a) describes how the Exchange calculates MOC and LOC imbalances, which is intended to provide market participants with a snapshot of the prices at which interest eligible to participate in the closing transaction would be executed in full against each other at the time the data feed is disseminated. Subsection (vi) of Rule 123C(4)(a) provides that tick sensitive MOC and LOC interest and LOC orders priced equal to the last sale can reduce the Buy or Sell Imbalance to bring the imbalance quantity as close to zero as possible. The Rule also provides that the volume of tick sensitive MOC and LOC orders eligible to reduce the imbalance shall not cause the imbalance to change to the other side.

Rule 123C(4)(a)(vi)(A) specifies that, in the event of a Buy Imbalance, only Sell Plus MOC orders, Sell Plus LOC orders priced equal to or below the last sale price, and Sell and Sell Short LOC orders priced equal to the last sale will be included to offset the imbalance, and that Sell Plus MOC and Sell Plus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions.

Rule 123C(4)(a)(vi)(B) specifies that, in the event of a Sell Imbalance, only Buy Minus MOC orders, Buy Minus LOC orders priced equal to or above the last sale price, and Buy LOC orders priced equal to the last sale will be included to offset the imbalance. The Rule also provides that Buy Minus MOC and Buy Minus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions.

To reflect the elimination of orders with a sell "plus" instruction and buy "minus" instructions, *i.e.*, tick-sensitive orders, and the fact that as proposed, Buy Minus Zero Plus orders would not be available for MOC or LOC Orders, the Exchange proposes to amend Rule 123C as follows:

- Amend Rule 123C(4)(a)(vi) to delete the phrase "tick sensitive MOC orders and LOC orders and" before "LOC orders priced equal to the last sale to bring the imbalance quantity as close to zero as possible." The Exchange also proposes to delete the last sentence in Rule 123C(4)(a)(vi), which provides that "[t]he volume of tick sensitive MOC and LOC orders eligible to reduce the imbalance shall not cause the imbalance to change to the other side."
- Amend Rule 123C(4)(a)(vi)(A) to remove references to Sell Plus MOC orders and Sell Plus LOC orders priced equal to or below the last sale price. The Exchange also proposes to delete the last sentence of the subsection (A), which provides that "Sell Plus MOC and Sell Plus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions."
- Amend Rule 123C(4)(a)(vi)(B) to remove references to Buy Minus MOC orders and Buy Minus LOC orders priced equal to or above the last sale price. The Exchange also proposes to delete the last sentence of the subsection (B), which provides that "Buy Minus MOC and Buy Minus LOC orders will be included to offset the imbalance only if such orders could be executed consistent with the terms of their tick restrictions."

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[10] *See* Rule 107B(a)—Equities.

Rule 1004

Finally, the Exchange proposes to amend Rule 1004 (Election of Buy Minus, Sell Plus and Stop Orders), which provides that automatic executions of transactions reported to the Consolidated Tape shall elect, among others, buy minus and sell plus orders electable at the price of such executions. The Rule further provides that any buy minus and sell plus orders so elected shall be automatically executed as market orders pursuant to Exchange rules.

To reflect the elimination of orders with a Sell "Plus" and Buy "Minus" instruction and retention of "Buy Minus Zero Plus" orders, the Exchange proposes to add "Zero Plus" after "buy minus" in Rule 1004, capitalize "buy minus," and delete the phrase "and sell plus" in two places. The Exchange also proposes to capitalize "market orders." As amended, Rule 1004 would allow for the automatic execution of Buy Minus Zero Plus orders electable at the price of such executions.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[11] of the Act, in general, and furthers the objectives of Section 6(b)(5),[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the Exchange believes that eliminating orders with a sell "plus" and buy "minus" instruction removes impediments to and perfects a national market system by simplifying functionality and complexity of its order types. The Exchange believes that eliminating these order types across all securities would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the removal of complex functionality.

The Exchange further believes that deleting corresponding references in Exchange rules to deleted order types also removes impediments to and perfects the mechanism of a free and open market by ensuring that members, regulators and the public can more easily navigate the Exchange's rulebook and better understand the orders types available for trading on the Exchange. Removing obsolete cross references also furthers the goal of transparency and adds clarity to the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but would rather remove complex functionality and obsolete cross-references, thereby reducing confusion and making the Exchange's rules easier to understand and navigate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2016–81 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–81. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–81 and should be submitted on or before September 21, 2016.

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[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Brent J. Fields,

Secretary.

[FR Doc. 2016–20959 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78697; File No. SR–BatsBZX–2016–53]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 19.6, Series of Options Contracts Open for Trading, To Allow Wednesday Expirations for SPY Options

August 26, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on August 25, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 19.6, entitled ''Series of Options Contracts Open for Trading,'' related to the Short Term Option Series (''STOS'') Program to allow Wednesday expirations for SPY options. The Exchange also proposes to make corresponding changes to Rule 16.1, entitled ''Definitions.'' The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to harmonize the Exchange's rules with the rules governing Short Term Options Series programs of other options exchanges. Specifically, the Exchange proposes to amend Rule 19.6, entitled ''Series of Options Contracts Open for Trading,'' related to the STOS Program to allow Wednesday expirations for SPY options. The Exchange also proposes to make certain corresponding changes to 16.1, entitled ''Definitions.'' The proposed rule change is based on the recent approval of a filing submitted by the BOX Options Exchange LLC (''BOX'').[5]

Currently, under the STOS Program, the Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next five Fridays, provided that such Friday is not a Friday in which monthly options series or Quarterly Options Series expire (''Short Term Option Series''). The Exchange is now proposing to amend its rule to permit the listing of options expiring on Wednesdays. Specifically, the Exchange is proposing that it may open for trading on any Tuesday or Wednesday that is a business day, series of options on the SPDR S&P 500 ETF Trust (''SPY'') to expire on any Wednesday of the month that is a business day and is not a Wednesday in which Quarterly Options Series expire (''Wednesday SPY Expirations'').[6] The proposed Wednesday SPY Expiration series will be similar to the current Short Term Option Series, with certain exceptions, as explained in greater detail below. The Exchange notes that having Wednesday expirations is not a novel proposal. Specifically, the Chicago Board Options Exchange, Incorporated (''CBOE'') recently received approval to list Wednesday expirations for broad-based indexes.[7]

In regards to Wednesday SPY Expirations, the Exchange is proposing to remove the current restriction preventing it from listing Short Term Option Series that expire in the same week in which monthly option series in the same class expire. Specifically, the Exchange will be allowed to list Wednesday SPY Expirations in the same week in which monthly option series in SPY expire. The current restriction to prohibit the expiration of monthly and Short Term Option Series from expiring on the same trading day is reasonable to avoid investor confusion. This confusion will not apply with Wednesday SPY Expirations and standard monthly options because they will not expire on the same trading day, as standard monthly options do not expire on Wednesdays. Additionally, it would lead to investor confusion if Wednesday SPY Expirations were not listed for one week every month because there was a monthly SPY expiration on the Friday of that week.

Under the proposed Wednesday SPY Expirations, the Exchange may list up to five consecutive Wednesday SPY Expirations at one time. The Exchange may have no more than a total of five Wednesday SPY Expirations listed. This is the same listing procedure as Short Term Option Series that expire on Fridays. The Exchange is also proposing to clarify that the five series limit in the current Short Term Option Series Program Rule will not include any Wednesday SPY Expirations.[8] This means, under the proposal, the Exchange would be allowed to list five Short Term Option Series expirations for SPY expiring on Friday under the current rule and five Wednesday SPY Expirations. The interval between strike prices for the proposed Wednesday SPY Expirations will be the same as those for the current Short Term Option Series. Specifically, the Wednesday SPY Expirations will have $0.50 strike intervals.

Currently, for each Short Term Option Expiration Date,[9] the Exchange is

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[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities and Exchange Act Release No. 78668 (August 24, 2016) (SR–BOX–2016–28).

[6] *See* proposed paragraph (g) of Interpretation and Policy .05 to Rule 19.6.

[7] *See* Securities Exchange Act Release No. 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (SR–CBOE–2015–106).

[8] *See* proposed changes to Interpretation and Policy .05 to Rule 19.6.

[9] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire on each of the next

Continued

limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges.[10] The thirty (30) series restriction shall apply to Wednesday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Wednesdays. As is the case with current Short Term Option Series, the Wednesday SPY Expiration series will be P.M.-settled. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Wednesday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange seeks to introduce Wednesday SPY Expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Wednesday expirations, similar to Friday expirations, would allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange is also proposing to amend the definition of Short Term Option Series contained in Exchange Rule 16.1(a)(57) to make clear that STOS includes Wednesday expirations and to conform to BOX Rule 100(a)(64). Specifically, the Exchange is amending the definition to expand Short Term Option Series to those listed on any Tuesday or Wednesday and that expire on the Wednesday of the next business week. If a Tuesday or Wednesday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday or Wednesday.

The Exchange believes that the introduction of Wednesday SPY Expirations will provide investors with a flexible and valuable tool to manage risk exposure, minimize capital outlays, and be more responsive to the timing of events affecting the industry. The proposed rule change is a competitive proposal designed to enable the Exchange to compete equally and fairly with other options exchanges in satisfying high market demand for weekly options and continuing strong customer demand to use STOS to execute hedging and trading strategies.

2. Statutory Basis

The rule changes proposed herein are consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[11] Specifically, the proposed change is consistent with Section 6(b)(5) of the Act,[12] because it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Wednesday SPY Expirations simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Wednesday SPY Expirations should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives. The Exchange believes that allowing Wednesday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Wednesday SPY Expirations in a continuous and uniform manner. Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Wednesday SPY Expirations in the same way it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, with respect to intermarket competition, the Exchange believes the proposal is pro-competitive and will allow the Exchange to compete more effectively with BOX, which has already adopted changes to its STOS programs that are substantially identical to the changes proposed by this filing.[14] In addition to BOX, the Exchange expects that other options exchanges will file similar proposals to adopt the changes in order to provide Wednesday SPY Expirations.

The Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner as existing Short Term Option Series. The Exchange believes that the proposal will result in additional investment options and opportunities to achieve the investment objectives of market participants seeking efficient trading and hedging vehicles, to the benefit of investors, market participants, and the marketplace in general.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16]

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five Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options Series expire ("Short Term Option Expiration Dates"). *See* Interpretation and Policy .05 to Rule 19.6.

[10] *See* current paragraph (a) of Interpretation and Policy .05 to Rule 19.6.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] *See supra* note 5.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intention to file the proposed rule change at least five business

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[17] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved BOX's substantially similar proposal to list and trade Wednesday SPY Expirations.[18] The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Wednesday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.[19] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsBZX–2016–53 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–53. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–53 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Brent J. Fields,

Secretary.

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days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] *See supra* note 5.

[19] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78675; File No. SR–OCC–2016–009]

Self-Regulatory Organizations; the Options Clearing Corporation; Notice of Filing of Proposed Rule Change Concerning the Options Clearing Corporation's Escrow Deposit Program

August 25, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 15, 2016, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of this proposed rule change by OCC is to improve the resiliency of OCC's escrow deposit program. OCC is proposing changes that are designed to: (1) Increase OCC's visibility into and control over collateral deposits made under the escrow deposit program; (2) strengthen clearing members' rights to collateral in the escrow deposit program in the event of a customer default to the clearing member; (3) provide more specificity concerning the manner in which OCC or clearing members would take possession of collateral in OCC's escrow deposit program; and (4) improve the readability of the rules governing OCC's escrow deposit program by consolidating all such rules into a single location in OCC's Rulebook.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to improve the resiliency of OCC's escrow deposit program. The changes would: (1) Increase OCC's visibility into and control over collateral deposits made under the escrow deposit program; (2) provide more specificity concerning the manner in which OCC would take possession of collateral in OCC's escrow deposit program in the event of a clearing member or custodian bank default; (3) clarify clearing members' rights to collateral in the escrow deposit program in the event of a customer default to the clearing member; and (4) improve the readability of the rules governing OCC's escrow deposit program by consolidating all such rules into a single location in OCC's Rulebook. Upon implementation of the proposed rule change, all securities collateral in OCC's escrow deposit program would be held at the Depository Trust Company ("DTC"), and custodian banks would only be allowed to hold cash collateral.

The narrative below is comprised of four sections. The first section provides a background of OCC's current escrow deposit program as well as an overview of the proposed changes to the rules and agreements that govern the escrow deposit program. The second section discusses the changes associated with: (1) Increasing OCC's visibility into and control over collateral deposits made under the escrow deposit program; (2) providing more specificity concerning the manner in which OCC would take possession of collateral in OCC's escrow deposit program in the event of a clearing member or custodian bank default; and, (3) clarifying clearing members' rights to collateral in the escrow deposit program in the event of a customer default to the clearing member as well as providing additional detail concerning the manner in which clearing members may take possession of such collateral. The third section discusses proposed technical and conforming changes to the rules and agreements governing the current escrow deposit program that would allow OCC to consolidate all such terms into a single location in OCC's Rulebook. The second and third sections also discuss changes that improve the readability of the rules governing OCC's escrow deposit program, which is primarily achieved by consolidating all such rules into a single location in OCC's Rulebook. The fourth section discusses the manner in which OCC proposes to transition from the current escrow deposit program to the new escrow deposit program, including the removal of certain rules and contractual provisions that would no longer be applicable to the new escrow deposit program.

Section 1: Background and Overview of Proposed Rule Changes

Background/Current Escrow Deposit Program

Each day OCC collects collateral from its clearing members in order to protect OCC and the markets it serves from potential losses stemming from a clearing member default. Approximately half of the collateral deposited by clearing members at OCC is deposited through OCC's escrow deposit program. Users of OCC's escrow deposit program are customers of clearing members who, through the escrow deposit program, are permitted to collateralize eligible positions directly with OCC (instead of with the relevant clearing member who would, in turn, deposit margin at OCC). Currently, collateral deposits made through OCC's escrow deposit program are characterized as either "specific deposits" or "escrow deposits." Specific deposits are deposits of the security underlying a given options position and are made through DTC by a clearing member on behalf of its customer (at the direction of the customer).[3] Escrow deposits are deposits of cash or securities made by a custodian bank on behalf of a customer of an OCC clearing member in support of an eligible options position. OCC's Rules currently contemplate two forms of escrow deposits: "third-party escrow deposits" and "escrow program deposits." Third-party escrow deposits are substantially similar to specific deposits except for the fact that third-party escrow deposits are made by a custodian bank, and not a clearing member. Third-party escrow deposits consist entirely of securities and, like specific deposits, are made through DTC. In order to effect third-party specific deposits, custodian banks must be DTC members. Escrow program deposits are bank deposits of eligible securities or cash, which are held at the custodian bank (versus third-party escrow deposits and specific deposits, which are held at DTC).

When a customer of a clearing member makes a deposit in lieu of margin through OCC's escrow deposit program, the relevant positions are excluded from the clearing member's margin requirement at OCC. The escrow deposit program therefore provides users of OCC's services with a means to more efficiently use cash or securities they may have available.

Overview of Rule Changes (Including Terminology Changes) and New Agreements

Rule Consolidation and Terminology Changes

Currently, the rules concerning OCC's escrow deposit program are located in OCC Rules 503, 610, 613 and 1801. Additionally, OCC and custodian banks participating in OCC's escrow deposit program enter into an Escrow Deposit Agreement ("EDA"), which also contains substantive provisions governing the program. OCC is proposing to consolidate all of the rules concerning the escrow deposit program, including the provisions of the EDA relevant to the revised escrow deposit program, into proposed Rules 610, 610A, 610B and 610C.[4] OCC believes that consolidating the many rules governing the escrow deposit program into a single location would significantly enhance the understandability and transparency of the rules concerning the escrow deposit program for current users of the program as well as any persons that may be interested in using the program in the future.

In connection with the above described rule consolidation, OCC is also proposing to rename the types of escrow deposits available within the escrow deposit program, as well as rename the term "approved depository" to "approved custodian." Specific deposits would now be called "member specific deposits," which are equity securities deposited by clearing members at DTC at the direction of their customers; third-party escrow deposits would now be called "third-party specific deposits," which are equity securities deposited by custodian banks at DTC at the direction of their customers; and, escrow program deposits would now be called, "escrow deposits," which are either cash deposits held at a custodian bank for the benefit of OCC, or Government securities deposited at DTC by custodian banks at the direction of their customers. The term "approved depository" would also be changed to "approved custodian" to eliminate any potential confusion with the term "Depository," which is defined in the Rules, to mean DTC.

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[3] For example, if customer XYZ holds a short position of options on AAPL, customer XYZ could, through its clearing member's DTC account, pledge shares of AAPL to OCC in order to collateralize such options position and not be charged margin by OCC.

[4] As described herein, OCC is proposing to eliminate the EDA based on such consolidation. When appropriate, and as described in more detail below, conforming changes were made to certain Rules as a result of OCC proposing to require that all non-cash deposits in the escrow deposit program be made through DTC (and not held at custodian banks).

New Rule Organization

With respect to the rules governing the escrow deposit program, proposed Rule 610 would set forth general terms and conditions common to all types of deposits permitted under the escrow deposit program. Specifically, proposed Rule 610: (1) Sets forth the different types of eligible positions for which a deposit in lieu of margin may be used, (2) sets forth operational aspects of the escrow deposit program such as the days and the times during which a deposit in lieu of margin may be made and where the different types of deposits in lieu of margin must be maintained (either DTC or a custodian bank), (3) provides the conditions under which OCC may take possession of a deposit in lieu of margin (from DTC or a custodian bank), and (4) describes OCC's security interest in deposits in lieu of margin.[5] Proposed Rule 610 is supplemented by: (1) Proposed Rule 610A for member specific deposits, (2) proposed Rule 610B for third-party specific deposits, and (3) proposed Rule 610C for escrow deposits. Proposed Rules 610A, 610B and 610C provide further guidance and specificity on the topics initially addressed in proposed Rule 610 (and delineated above) as they relate to member specific deposits, third-party specific deposits and escrow deposits, respectively.

The new rule structure differs from the existing rule structure in that existing Rules 503, 610, 613 and 1801 discuss topics concerning deposits in lieu of margin (such as withdrawal, roll-over[6] and release) in general terms and without regard to the type of deposit in lieu of margin. The existing rule structure also does not provide operational details of the escrow deposit program. The new rule structure discusses each aspect of OCC's escrow deposit program by type of deposit in lieu of margin (member specific deposits, third-party specific deposit or escrow deposits) as well as provides operational details concerning the program. OCC believes that the more detailed presentation of the new rules concerning the escrow deposit program enhances the understandability of the program to all users, and potential users, of the program because all such persons will be able to better understand how topics apply by type of deposit in lieu of margin and with regard to the operational differences between each type of deposit in lieu of margin.

Agreements Concerning the Escrow Deposit Program

In addition to the above-described Rule changes, many provisions of the EDA would be moved into the Rules. Accordingly, OCC is proposing to eliminate the EDA and replace it with a simplified agreement entitled the "Participating Escrow Bank Agreement."[7] The Participating Escrow Bank Agreement would provide that custodian banks are subject to all terms of the Rules governing the revised escrow deposit program,[8] as they may be amended from time to time.[9] The Participating Escrow Bank Agreement would contain eligibility requirements for custodian banks, including representations regarding the custodian bank's Tier 1 Capital,[10] and provide OCC with express representations concerning the bank's authority to enter into the Participating Escrow Bank Agreement.[11] Moreover, standard contractual provisions concerning topics such as assignment, governing law and limitation of liability have been enhanced in the Participating Escrow Bank Agreement when compared to the EDA.[12] OCC is also proposing to move notification requirements into proposed Rule 610C(l), which is an enhancement of Section 7 of the EDA that requires custodian banks to provide notice to OCC only when there are changes to the "authorized persons" and changes to the address of the bank. Proposed Rule 610C(l) would require escrow banks to provide OCC with notices of material changes to the bank (in additional to items such as changes of authorized persons and the address of bank, as currently required under Section 7 of the EDA).

OCC, under Proposed Rule 610C(b), would also require customers wishing to deposit cash collateral and custodian banks holding escrow deposits comprised of cash to enter into a tri-party agreement involving OCC, the customer and the applicable custodian bank ("Tri-Party Agreement," attached hereto as Exhibit 5B). The Tri-Party Agreement governs the customer's use of cash in the program, confirms the grant of a security interest in the customer's account to OCC and the relevant clearing member, as set forth in proposed Rule 610C(f), and causes customers of clearing members to be subject to all terms of the Rules governing the revised escrow deposit program.[13] Each custodian bank entering into the Tri-Party Agreement ("Tri-Party Custodian Bank"), would agree to follow the directions of OCC with respect to cash escrow deposits without further consent by the customer.[14] As discussed in greater detail below, use of the Tri-Party Agreement significantly enhances OCC's rights concerning cash escrow deposits, and provides OCC with greater certainty regarding its rights to cash escrow deposits in the event of a customer or clearing member default.

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[5] OCC would continue to maintain a perfected security interest in deposits in the escrow deposit program under the proposed Rules notwithstanding changes to the location of the rules that perfect such security interest. OCC's security interest in securities deposits in the escrow deposit program, which are held at DTC, is perfected by operation of DTC's rules. OCC's security interest in cash deposits in the escrow deposit program is perfected under proposed Rules 610C(i), 610C(j) and 610C(k), which replace Sections 3.3, 3.4, 4.3, 4.4, 5.3, 5.4 and 21 of the EDA. Proposed Rule 610(g) also concerns OCC's security interest in deposits in escrow deposit program.

[6] A "roll-over" occurs when a customer chooses to maintain an existing escrow deposit after the options supported by the escrow deposit expires, or are closed-out, and the customer re-allocates the escrow deposit to a new options position.

[7] The Participating Escrow Bank Agreement is attached to this filing as Exhibit 5A, with changes from the EDA marked. Custodian banks participating in the revised escrow deposit program are defined as "Participating Escrow Banks" in the Participating Escrow Bank Agreement, and such banks must also be an Approved Custodian pursuant to proposed Section 1.A(13) of OCC's By-Laws. In addition, and as described above, certain provisions of the EDA are proposed to be incorporated into OCC's Rules; however, no rights or obligations of either OCC or a custodian bank would change solely as a result of such an incorporation.

[8] The Rules governing the revised escrow deposit program are proposed Rules 610, 610A, 610B and 610C.

[9] Under the Participating Escrow Bank Agreement, however, OCC will agree to provide custodian banks with advance notice of material amendments to the Rules relating to deposits in lieu of margin and custodian banks will have the opportunity to withdraw from the escrow deposit program if they object to the amendments. As a general matter, the Participating Escrow Bank Agreement will not be negotiable, although OCC may determine to vary certain non-material terms in limited circumstances.

[10] OCC recently enhanced the measurement it uses—Tier 1 Capital instead of shareholders' equity—to establish minimum capital requirements for banks approved to issue letters of credit that may be deposited by clearing members as a form of margin asset. *See* Securities Exchange Act Release No. 74894 (May 7, 2015), 80 FR 27431 (May 13, 2015) (SR–OCC–2015–007). For the reasons set forth in SR–OCC–2015–007, OCC is proposing to adopt the same standard with respect to custodian bank escrow deposits.

[11] These provisions include, but are not limited to, Sections 1.1 and 1.2 of the EDA.

[12] Sections 2.1, 2.2, 3.5, 3.6, 3.8, 4.7, and 5.6, 6 and 7 of the EDA would be removed entirely since they are no longer needed under OCC's revised escrow deposit program. These provisions concern a custodian bank's movement of securities escrow collateral; such collateral would be deposited at DTC under the revised escrow deposit program (as described below). Section 2.3 of the EDA would also be removed in its entirety because escrow deposits would not be permitted for equity calls in the revised escrow deposit program. Additionally, the concept of cash settlements concerning escrow deposits would not be included in the revised escrow deposit program and, as a result, Sections 15, 16, 17 and 18(b) to 18(d) would be removed in their entirety.

[13] The Rules governing the revised escrow deposit program are proposed Rules 610, 610A, 610B and 610C.

Section 2: Transparency and Controls, Taking Possession of Collateral, and Clearing Member Rights to Collateral

Transparency and Control Over Collateral Included in Escrow Deposits

Currently, securities deposits in the escrow deposit program are held at either DTC or a custodian bank, and cash deposits in the escrow deposit program are held at a custodian bank. In the case of either cash or securities held at a custodian bank, OCC relies on the custodian bank to verify the value and control of collateral since OCC does not have any visibility into relevant accounts. OCC is proposing to require that all securities deposited within the escrow deposit program, regardless of the type of deposit, be held at DTC.[15] Additionally, OCC is proposing to require Tri-Party Custodian Banks to provide OCC with view access into the account in which the deposit is held.

Holding securities escrow deposit program collateral at DTC would provide OCC with increased visibility into the collateral within the escrow deposit program because OCC would be able to use its existing interfaces with DTC to view, validate and value collateral within the escrow deposit program in real time, allowing OCC to perform the controls for which it currently relies on the custodian banks. It would also provide OCC with the ability to obtain possession of deposited securities upon a clearing member default by issuing a demand of collateral instruction through DTC's systems, without the need for custodian bank involvement. Furthermore, a clearing member would have the ability to obtain possession of deposited securities upon a customer default in a similar manner by notifying OCC of such customer default and submitting a request for delivery of such deposited securities (OCC's and clearing members' ability to take possession of a deposit within the escrow deposit program is discussed in greater detail below). OCC does not believe that requiring use of DTC to deposit securities escrow collateral presents a material change for users of OCC's escrow deposit program because such users currently use DTC to effect certain types of deposits in lieu of margin under the current escrow deposit program.[16]

Cash collateral pledged to support an escrow deposit would continue to be facilitated through the existing program interfaces; however, for increased security, any pledges of cash would be required to be made in a customer's account at the Tri-Party Custodian Bank that is used solely for the purpose of making escrow deposits. As described above, under the proposed changes OCC would require Tri-Party Custodian Banks and customers to enter into a Tri-Party Agreement in order to provide legal certainty concerning this arrangement. Further, and as set forth in the Tri-Party Agreement, each Tri-Party Custodian Bank would agree to disburse funds from the pledged account only at OCC's direction. From an operational perspective, each Tri-Party Custodian Bank would provide OCC with online view access to each customer's cash account designated for the escrow deposit program, allowing visibility into transactional activity and account balances. OCC would not process a cash escrow deposit in its systems until it sees the appropriate amount of cash deposited in the designated bank account at the Tri-Party Custodian Bank. This process ensures that OCC does not rely on a third party to value, or warrant the existence of, collateral within the escrow deposit program. The Tri-Party Agreement, in connection with the new cash collateral structure, would provide OCC with additional transparency and control over cash collateral under the revised escrow deposit program.

In order to effect the foregoing, OCC is proposing to adopt proposed Rules 610A(a), 610B(a), 610C(b) and 610C(c). Proposed Rules 610A(a) and 610B(a), Effecting a Member Specific Deposit and Effecting a Third-Party Specific Deposit, respectively, require that member specific deposits and third-party specific deposits must be made through DTC, and are largely based upon existing Rule 610(e), which discusses effecting deposits in lieu or margin generally. Language has been added to each proposed rule to more accurately articulate that member specific deposits and third-party specific deposits must be made through DTC and the party that is required to effect each type of deposit (*i.e.*, a clearing member or a third-party depository). In the case of member specific deposits and third-party specific deposits, which are already made through DTC, OCC believes that proposed Rules 610A(a) and Rule 610B(a) are rules that clarify existing practices and provide additional operational detail to users of the escrow deposit program (*i.e.*, member specific deposits and third-party specific deposits must be made through DTC's EDP Pledge System and clearing members are required to maintain records of such deposits). Proposed Rules 610C(b) and 610C(c), Manner of Holding and Method of Effecting Escrow Deposits, respectively, are largely based upon existing Rules 610(d), 610(g), 1801(d) and 1801(g), as well as Section 8 of the EDA with language added to more accurately articulate that securities escrow deposits must be made through DTC and cash must be deposited through a Tri-Party Custodian Bank, and provide operational detail concerning effecting escrow deposits. Moreover, OCC is proposing to adopt new Rule 610(e) in order to specify that all types of deposits in the escrow deposit program may be made only during the time specified by OCC. The purpose of specifying the time frames in which participants are allowed to effect deposits in the escrow deposit program is to facilitate OCC daily margin processing and ensure that all of the positions it guarantees are timely collateralized.[17]

In addition to the above, and with respect to escrow deposits only, OCC is proposing enhancements to its process of ensuring that customers meet initial and maintenance minimums.[18] Specifically, under the revised escrow deposit program, in the event a customer falls below the maintenance minimum, the custodian bank, pursuant to the Participating Escrow Bank Agreement, would be required to ensure that the customer deposits additional collateral or escalate the matter to OCC. In addition to such notification requirement, OCC would also implement automated processes to ensure that escrow deposits meet required initial and maintenance minimums. In the event the matter is escalated to OCC or OCC's systems identify a shortfall, OCC would: (1) Demand that the relevant clearing member post additional margin to cover the margin requirement on the applicable position, and (2) if the relevant clearing member fails to satisfy such a demand for additional margin, OCC would close-out the applicable position and demand the escrow deposit from DTC or the Tri-Party Custodian Bank, as applicable, under its existing authority pursuant to Rule 1106. This process is much more robust than the current process concerning maintenance minimums in that OCC currently relies entirely on custodian banks holding escrow deposits to ensure the customer deposits additional collateral, as necessary, to meet initial and maintenance minimums. OCC believes that the proposed new process is more streamlined and efficient because OCC would not have to rely entirely on a custodian bank to ensure customers comply with initial and maintenance minimums.

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[14] OCC has determined to use this cash account structure as a result of a series of discussions with certain custodian banks involved in the cash portion of the escrow deposit program, as described in Item 5 below. The intended structure would permit a greater number of customers to participate in the escrow deposit program than, for example, a commingled "omnibus" account structure at each custodian bank, which would preclude the participation of customers subject to restrictions under the Investment Company Act of 1940 requiring segregation of a registered investment company's funds.

[15] OCC has discussed the proposed rule changes to the escrow deposit program with DTC and, based on feedback from DTC, no concerns were communicated to OCC by DTC regarding the proposed rule changes. DTC has also indicated that the proposed rule changes to the escrow deposit program are consistent with DTC's operations.

[16] Specifically, users of OCC's escrow deposit program would use DTC's Collateral Loan Services, which is described at: *http://www.dtcc.com/products/training/helpfiles/settlement/settlement_help/help/collateral_loans.htm.*

[17] In the event a deposit in the escrow deposit program is not timely made, OCC would collect margin from the relevant clearing member.

[18] Initial and maintenance minimums do not apply to member specific deposits and third-party specific deposits since the clearing member or custodian bank, as applicable, is pledging the security that is deliverable upon exercise of the germane options position.

In order to implement the foregoing within the new rules concerning the escrow deposit program, OCC is proposing to adopt Rules 610C(g) and 610C(h) that concern the initial and maintenance minimum escrow deposit values required by OCC as well as actions OCC is permitted to take in the event an escrow deposit falls below a required amount. These proposed rules are based on existing Rules 1801(c) and 1801(e) as well as Sections 3.2, 4.2, 5.2, 3.7, 4.8 and 5.7 of the EDA.[19] With respect to the computation of initial and maintenance minimums, proposed Rules 610C(g) and 610C(h) would explain the formula through which OCC computes the initial and maintenance minimum for a given options position, with the specific percentage applicable to such calculation provided to participants in the escrow deposit program in a schedule posted on OCC's Web site. With respect to the effects of a failure to meet maintenance minimums, proposed Rule 610C(h) sets forth the conditions under which OCC would close out a given escrow deposit should it fall below the requisite maintenance minimum. Proposed Rule 610C(h) would also provide OCC with the authority to use the cash and securities included within the escrow deposit to reimburse itself for costs incurred in connection with the close-out. OCC believes that by virtue of their proposed new location in the rules, as well as the additional detail provided in the proposed rules, all participants, and potential participants, in OCC's escrow deposit program would better understand the rules concerning initial and maintenance minimums, as they relate to escrow deposits, under the enhanced escrow deposit program (versus under the current escrow deposit program).

OCC's Rights to Collateral in the Escrow Deposit Program in the Event of a Clearing Member or Bank Default

The proposed Rules would enhance OCC's default management regime as it relates to the escrow deposit program by more specifically delineating the conditions under, and the process through which, OCC would take possession of collateral within the escrow deposit program should a clearing member or custodian bank default. Specifically, proposed Rules 610A(b), 610B(f), 610C(q) and 610C(r) provide that in the event of a clearing member or custodian bank default OCC would have the right to direct DTC to deliver the securities included in a member specific deposit, third-party specific deposit or escrow deposit to OCC's DTC participant account for the purpose of satisfying the obligations of the clearing member or reimbursing itself for losses incurred as a result of the failure, as applicable. Similarly, pursuant to proposed Rules 610C(q) and 610C(r) OCC would have the right in the event of a Tri-Party Custodian Bank default to take possession of cash included within an escrow deposit for the same purposes. In the event of a custodian bank default, pursuant to proposed Rule 610C(r) OCC would have the right to remove the custodian bank from the escrow deposit program, prohibit the custodian bank from making new escrow deposits, disallow withdrawals with respect to existing deposits, close out short positions covered by escrow deposits at the defaulted custodian bank and use such escrow deposits to reimburse itself for the costs of the close-out, or disregard or require the withdrawal of existing escrow deposits.

Proposed Rules 610A(b), 610B(f) and 610C(q) concern OCC's rights to member specific deposits, third-party specific deposits and escrow deposits, respectively, in the event of a clearing member default. They would provide a more specific description of OCC's rights to a third-party specific deposit during a default than existing Rule 610(k) and Section 18 of the EDA. However, the additional specificity that would be provided in proposed Rules 610A(b), 610B(f) and 610C(q) would not change OCC's nor clearing members' rights or obligations regarding member specific, third-party specific or escrow deposits in the event of a clearing member default. Proposed Rule 610C(r) addresses OCC's rights in the event of a custodian bank default and is based on existing Rules 613(h) and 1801(k). Proposed Rule 610C(r) would clarify OCC's existing operational practices when a custodian defaults (*i.e.,* demand monies, not allow new deposits, etc., as described immediately above), but does not change any of the rights of OCC, clearing members or custodian banks set forth in existing Rules 613(h) and 1801(k).

In addition to the above-described proposed rule changes, OCC is proposing to amend Rule 1106 to set forth the treatment of deposits in the escrow deposit program in the event of a suspension of a clearing member. Rule 1106(b)(2) would be amended to provide that OCC may close out a short position of a suspended clearing member covered by a member specific, third-party specific or escrow deposit, subject to the ability of the suspended clearing member or its representative to transfer the short position to another clearing member under certain circumstances. Further, current Rule 1106(b)(3) would be combined with Rule 1106(b)(2) and amended to set forth OCC's right to take possession of the cash and/or securities included within an escrow, member specific or third-party specific deposit for the purpose of reimbursing itself for costs incurred in connection with the close-out of a short position covered by the deposit. These proposed amendments to Rule 1106 are consistent with proposed Rules 610B(f), 610C(q) and 610C(r).

Clearing Members' Rights to Collateral in the Escrow Deposit Program

Clearing members' rights to escrow deposits and third-party specific deposits would be clarified under the proposed rules. While clearing members have secondary lien rights to the escrow deposits of their customers under the current escrow deposit program, OCC is proposing to add several rules that would clarify these rights and provide additional guidance to clearing members regarding operational steps that would need to be taken in order to exercise their secondary lien rights. Specifically, OCC is proposing to add Rules 610B(c) and 610C(f) to delineate the rights of a clearing member as they relate to third-party specific deposits and escrow deposits. Proposed Rules 610B(c) and 610C(f) would provide for the grant of a security interest by the customer to the clearing member with respect to any given third-party specific deposit and escrow deposit, as applicable. The Rules would further provide that any such security interest of a clearing member in an escrow deposit would be subordinated to OCC's interest. For purposes of perfecting a clearing member's security interest under the Uniform Commercial Code ("UCC"), OCC would obtain control over the security both on its own behalf and on behalf of the relevant clearing member, with clear subordination of the clearing member's interest to OCC's interest. In the event OCC had to direct delivery of the security to the clearing member, OCC would do so on the clearing member's behalf. Proposed Rules 610B(c) and 610C(f) would better codify clearing members' secondary lien rights to third-party specific deposits and escrow deposit than they are currently codified in Section 21 of the EDA, without changing any clearing member rights or obligations. OCC believes that such a codification would provide more transparency regarding clearing members' secondary lien rights under the enhanced escrow deposit program because all users and potential users of OCC's escrow deposit program would be able to easily identify and understand the rules concerning clearing members' secondary lien rights in a single location within OCC's publicly available Rulebook.

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[19] OCC is proposing to eliminate the concept of "substitutions" of escrow deposit collateral (located in Sections 4.7 and 5.6 of the EDA)—instead a given escrow deposit must at all times must meet the minimum amount (as set forth in proposed Rules 610(g)(1) and (2)) and OCC would permit any excess amount to be withdrawn.

Additionally, OCC is proposing to add several procedural rules that would set forth the process by which clearing members could exercise their secondary lien rights in a given deposit in the escrow deposit program. Proposed Rules 610C(d), 610C(o), 610C(p) and 610C(s), relating to escrow deposits, and proposed Rules 610B(d) and 610B(e), relating to third-party specific deposits, would provide that, in the event of a customer default to a clearing member, the clearing member would have the right to request a "hold" on a deposit. The hold would prevent the withdrawal of deposited securities or cash by a custodian bank or the release of a deposit that would otherwise occur in the ordinary course. Subsequent to placing a hold instruction on a deposit, a clearing member would have the right to request that OCC direct delivery of the deposit to the clearing member through DTC's systems in the case of securities, or an instruction to the Tri-Party Custodian Bank in the case of cash. Providing clearing members with transparent instructions regarding how to place a hold instruction on, and direct delivery of a deposit within the escrow deposit program, would significantly enhance the current escrow deposit program.

OCC is also proposing to adopt Rules 610B(e) and 610C(s), which would protect OCC in the event that it delivers a third-party specific deposit or escrow deposit to a clearing member. Under proposed Rules 610B(e) and 610C(s), a clearing member making a request for delivery would be deemed to have made the appropriate representations to OCC that the clearing member has a right to take possession of the deposited securities or cash and would agree to indemnify OCC against losses resulting from a breach of these representations or the delivery of the deposit. A clearing member would also be required to provide documentation regarding its right to possession of the securities or cash as OCC may reasonably request.

Section 3: Techincal[sic] and Conforming Changes to OCC'S Rules

OCC also proposes a number of technical, conforming and structural changes in order to move the majority of the terms governing the escrow deposit program into one section in its Rulebook. OCC believes that changes to proposed Rules 610, 610A, 610B and 610C, described in greater detail below, are either non-substantive or conforming changes that do not alter the current rights or obligations of OCC, clearing members or participants in the escrow deposit program.

Proposed Rule 610—Deposits in Lieu of Margin (General Provisions)

Proposed Rule 610 contains general provisions applicable to the escrow deposit program. Specifically, proposed Rule 610(a) replaces existing Rule 610(a) and sets forth general provisions of the escrow deposit program including: (1) Who may participate in the escrow deposit program, (2) the types of positions included in the escrow deposit program, (3) the types of deposits in the escrow deposit program, and (4) the collateral that is eligible for the escrow deposit program. Proposed Rule 610(b) replaces existing Rule 610(b) and provides further specificity with respect to the types of options positions included within OCC's escrow deposit program.[20] This additional specificity clarifies OCC's existing rules and provides more transparency to users and potential users of OCC's escrow deposit program. Proposed Rule 610(c), which is not derived from an existing rule, clarifies OCC's existing practice that OCC will disregard a member specific deposit or a third-party specific deposit if such deposit is no longer eligible to be delivered upon the exercise of the associated stock option contract. Proposed Rule 610(d), which replaces existing Rules 610(c) and 1801(l), requires that deposits within the escrow deposit program be made in accordance with applicable laws and regulations, and be appropriately authorized. Proposed Rule 610(f), which replaces existing Rule 610(l), would clarify OCC's right to use deposits within the escrow deposit program until such deposits are withdrawn. Proposed Rule 610(f) is supplemented by proposed Rules 610A, 610B and 610C with respect to member specific, third-party specific and escrow deposits. Proposed Rule 610(g) codifies OCC's security interest in deposits within the escrow deposit program.

Proposed Rule 610A—Member Specific Deposits

Proposed Rule 610A clarifies many of the current rules concerning the escrow deposit program as they relate to member specific deposits. For example, proposed 610A(c) describes the process by which a clearing member may withdraw a member specific deposit (*i.e.*, effecting a withdrawal or release through DTC's EDP Pledge System and ensuring that its margin requirement at OCC is met). While this issue is addressed in existing Rule 610(j) in general terms, OCC believes that the additional operational details regarding its existing processes in proposed Rule 610A(c), along with its inclusion in proposed Rule 610A, further clarify how those existing processes apply to member specific deposits as opposed to other types of deposits in lieu of margin in existing Rule 610.[21] Proposed Rule 610A(d) also establishes that member specific deposits may be "rolled-over," a concept that is not specifically set forth in existing Rule 610 but has historically applied in connection with member specific deposits (formerly specific deposits).

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[20] As described in greater detail below, proposed Rules 610(a) and 610(b) are supplemented by proposed Rules 610A, 610B and 610C.

[21] Proposed Rule 610A(c) supplements proposed Rule 610(f).

Proposed Rule 610B—Third-Party Specific Deposits

Proposed Rule 610B clarifies many of the current rules concerning third-party specific deposits. For example, Proposed Rule 610B(b) addresses rollovers of a third-party specific deposit and replaces existing Rules 613(a) and Section 9 of the EDA, and articulates how to rollover third-party specific deposits by its inclusion within Rule 610B. Withdrawals and releases of third-party specific deposits are addressed in proposed Rule 610B(d), which is based on existing Rules 613(b) and 613(f). Specifically, releases and withdrawals of third-party specific deposits would be effected through DTC's EDP Pledge System, subject to the clearing member's margin requirement being met, the clearing member's approval of the release or withdrawal, and the absence of a "hold" instruction. In addition, proposed Rule 610B(g) seeks to provide a more detailed description of the effect of a release of a third-party specific deposit than the applicable portions of existing Rule 613(i).

Proposed Rule 610C—Escrow Deposits

Proposed Rule 610C, which is based on existing Rule 1801(a), would clarify the current rules concerning escrow deposits. For example, the introductory paragraph of proposed Rule 610C would provide a more detailed overview of a custodian bank's role in the escrow deposit program, specifying such a bank's role in effecting escrow deposits, and would describe eligible positions as they relate to escrow deposits. Proposed Rules 610C(a) through 610C(e) and proposed Rule 610C(t) concern eligible collateral, the manner in which escrow deposits are to be held, and withdrawing an escrow deposit and rolling over an escrow deposit. These operational rules are based on: (1) Existing Rules 610(g) and 1801(b) and Sections 3.1, 4.1 and 5.1 of the EDA with respect to eligible collateral (proposed Rule 610C(a)); (2) existing Rules 610(j) and 1801(i), and Sections 10 and 20 of the EDA with respect to withdrawing an escrow deposit (proposed Rule 610C(d)); (3) existing Rule 613(i) with respect to the effect of a release or withdrawal of an escrow deposit (proposed Rule 610C(t)); and (4) existing Rule 613(a) and Section 9 of the EDA with respect to rollovers of an escrow deposit (Proposed Rule 610C(e)).

In order to provide additional transparency concerning representations that custodian banks are deemed to make when effecting an escrow deposit, OCC is proposing to move several contractual provisions of the EDA into proposed Rules 610C(i), 610C(j) and 610C(k). Specifically: (1) Proposed Rule 610C(i), which concerns agreements and representations a custodian bank is deemed to have made when effecting an escrow deposit, is based upon Sections 1.6 and 4.6 of the EDA; (2) proposed Rule 610C(j), which concerns representations and warranties a custodian bank is deemed to make when giving an instruction to OCC and is based upon Sections 1.3, 1.4, 1.5, 1.6, 1.7 and 1.8 of the EDA; and (3) proposed Rule 610C(k), which concerns agreements a custodian bank is deemed to make when giving an instruction to OCC and is based upon Sections 4, 5 and 21 of the EDA. Moreover, and in addition to locating deemed representations of custodian banks in the Rules, proposed Rules 610C(i), 610C(j) and 610C(k) contain language that perfects OCC's security interest in escrow deposits under Section 9 of the UCC, and replace Sections 3.3, 3.4, 4.3, 4.4, 5.3 and 5.4 of the EDA.[22] OCC believes that by locating the above-described provisions in the Rules, all users and potential users of OCC's escrow deposit program would better understand the relationship between OCC and custodian banks.

Proposed Rules 610C(m), 610C(n), 610C(o) and 610C(p) concern the exercise of options positions collateralized by escrow deposits and the release of escrow deposits upon expiration. As with other parts of proposed Rule 610C, OCC believes that the location of proposed Rules 610C(m), 610C(n), 610C(o) and 610C(p) provides all users and potential users of OCC's escrow deposit program with a more transparent understanding of how exercises of options positions affect escrow deposits as well as the manner in which OCC would release an escrow deposit upon the expiration of an options position. Similar to other parts of Rule 610C, proposed Rules 610C(m), 610C(n), 610C(o) and 610C(p) are based on existing Rules of OCC as well as the EDA.[23] Proposed Rule 610C(m) concerns reports OCC provides regarding escrow deposits and is based upon existing Rules 613(d) and 613(e) as well as Sections 11, 12 and 13 of the EDA. Proposed Rules 610C(n), 610C(o) and 610C(p), which concern assignments of exercises and releases of escrow deposits upon expiration is based upon existing Rules 613(f) and 1801(j) and Section 14 of the EDA.

Section 4: Transition Period

For the administrative convenience of clearing members, custodian banks and customers, the existing Rules governing deposits in lieu of margin would remain in effect, in parallel with the proposed Rules, for a transition ending November 30, 2017. During this transition period, deposits in lieu of margin could be made under either the existing Rules or the proposed Rules. This will eliminate the need of all clearing members to provide new collateral on a single date in the absence of a transition period. After the transition period, proposed Rules 610, 610A, 610B and 610C would provide the sole means of making deposits in lieu of margin and existing Rules 613 and 1801 would be removed from the Rulebook. In connection with the transition, existing Rule 610 would be re-designated as 610T to indicate that it is a temporary rule, and would become ineffective and removed after the transition period. Furthermore, following the transition period, existing Rule 503, which addresses instructions that call for the payment of a premium by or to the clearing member for whose account the deposit is made, would be removed from the Rules because these instructions would no longer be permitted under the revised escrow deposit program since this aspect of the program has not been used for a number of years.[24] In addition, Government securities would be given full market value under the revised escrow deposit program and therefore existing Rule 610(h) would be removed from the Rules after the transition period.

2. Statutory Basis

OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[25] because it would ensure the safeguarding of securities and funds which are in the custody and control of OCC. As described above, the proposed rule change would increase OCC's visibility into and control over cash and securities deposits made in OCC's escrow deposit program. Deposits in OCC's escrow deposit program collateralize open securities positions guaranteed by OCC and protect OCC and market participants from the risk associated with a default of a clearing member. The proposed rule change would better ensure that OCC could verify that deposits of both cash and securities within OCC's escrow deposit program sufficiently collateralize germane short options position(s). In addition, OCC would: (1) Be able to use its existing functionality with DTC to more quickly take possession of such deposits without involving custodian banks in the event of a clearing member default, and (2) obtain a contractual commitment from [sic] Tri-Party Custodian Bank that they would disperse cash within the escrow deposit program to OCC at OCC's direction. OCC believes that these features of the revised escrow deposit program would reduce potential losses that may occur as a result of a clearing member default. As a result of the foregoing, the proposed rule change would better ensure the safeguarding of securities and funds that are in the custody and control of OCC.

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[22] The primary UCC-related provisions in the proposed Rules include Rules 610C(j)(1), 610C(j)(9) and 610C(k)(1), which provide for the perfection of OCC's security interest in deposits consisting of securities under UCC Sections 9–106 and 9–314; Rules 610C(j)(1), 610C(j)(10), and 610C(k)(2), which provide for the perfection of OCC's security interest in deposits consisting of cash under UCC Sections 9–104, 9–312 and 9–314; and Rules 610C(i)(1), 610C(i)(2) and 610C(j)(3), which support the first priority of OCC's security interest by preventing competing liens or claims.

[23] As discussed in Section 3 above, Rules 610C(n) and 610C(p) contain language that prevents the release of an escrow deposit in the event such deposit is subject to a hold instruction, which is a proposed enhancement to the escrow deposit program.

[24] For the purposes of clarity, existing Rules 613(c), 613(g), 613(h), 613(j) address the same topic and would be removed from OCC's Rulebook following the transition period without being migrated into a proposed Rule.

[25] 15 U.S.C. 78q–1(b)(3)(F).

OCC also believes that the proposed rule change is consistent with Rule 17Ad–22(d)(3), which requires OCC to hold assets in a manner that minimizes risk of loss or delay or in access to them.[26] Specifically, and with respect to non-cash collateral, all non-cash collateral in the escrow deposit program would be held at DTC thereby allowing OCC to validate and value collateral in real time and quickly obtain possession of deposited securities by issuing a transfer instruction through DTC's systems in an event of default without involving custodian banks. With respect to cash collateral, all such collateral would be held in an escrow deposit program specific account at a Tri-Party Custodian Bank, OCC would have view access into such account, and OCC would obtain a contractual commitment from the Tri-Party Custodian Banks that they would disperse cash within the escrow deposit program to OCC at OCC's direction. By more widely utilizing its existing infrastructure for non-cash collateral in the escrow deposit program, as well as by obtaining specific agreements regarding its right to take possession of cash collateral, OCC will be able to more quickly take possession of collateral in the escrow deposit program in the event of a clearing member default that would, in turn, reduce potential losses to OCC, other clearing members and market participants. Moreover, OCC believes that the proposed rule change is consistent with the requirement in Rule 17Ad–22(d)(11)[27] that clearing agencies establish, implement, maintain and enforce policies and procedures reasonably designed to make key aspects of their default procedures publicly available, because the substantive terms of the escrow deposit program, and specifically the rules concerning default management, would be incorporated into OCC's Rules, which are publicly available on OCC's Web site, rather than in private agreements.

(B) Clearing Agency's Statement on Burden on Competition

The proposed rule change would reflect changes to the Rules governing OCC's escrow deposit program and, more generally, amend the Rules to more clearly identify the three forms of deposits in lieu of margin: (1) Escrow deposits, (2) third-party specific deposits and (3) member specific deposits. The proposed rule change would impose a burden on competition that is necessary and appropriate in furtherance of the Act.[28] In particular, a burden would be imposed on Tri-Party Custodian Bank[sic] in light of the requirement that cash included within an escrow deposit be held in an account of the relevant customer at the Tri-Party Custodian Bank pursuant to a Tri-Party Agreement. This requirement may limit certain custodian banks' participation in the escrow deposit program because the escrow deposit program would now require a Tri-Party Custodian Bank to have the technological capability to allow both OCC and customers of clearing members to have view access into bank accounts within the escrow deposit program. However, OCC believes that the resulting burden on competition is both necessary and appropriate in furtherance of the Act because OCC's view access into bank accounts within the escrow deposit program provides OCC additional transparency over cash collateral. As described in Item 3 above, by obtaining view access into bank accounts within the escrow deposit program OCC would not have to rely on Tri-Party Custodian Bank[sic] to value, or warrant the existence of, cash collateral within the escrow deposit program. OCC believes that obtaining such additional transparency over cash collateral is necessary and appropriate in furtherance of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Communications With Custodian Banks

In light of the substantial changes proposed to the escrow deposit program, OCC has sought to keep custodian banks informed regarding the proposed rule changes. These communications began in January and February 2012, when OCC notified each custodian bank of the proposal to restructure the escrow deposit program. As part of this notification, OCC informed each custodian bank of (1) OCC's intention to require that security pledges be made through DTC, (2) the percentage of cash used in the escrow deposit program and (3) the potential elimination of cash deposits.[29]

In June through August 2012, OCC provided a PowerPoint presentation to each custodian bank summarizing proposed rule changes to the escrow deposit program. This presentation included an explanation of the reasons for the proposed rule changes, including the desire to enhance and strengthen the escrow deposit program and increase collateral transparency. The presentation also included a discussion of changes to the validation and valuation of collateral, and the calculation of contract quantities based on the collateral that has been pledged.

In April and May 2013, OCC provided each custodian bank with an operational overview of the restructured escrow deposit program in the form of a PowerPoint presentation. This presentation covered: Eligible option types, types of eligible supporting collateral, required collateral value calculations for option contact coverage, valuation of supporting collateral, asset management locations/processing of supporting collateral, and validation and valuation of supporting collateral and calculation of option contract coverage.

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[26] 17 CFR 240.17Ad–22(d)(3)

[27] 17 CFR 240.17Ad–22(d)(11).

[28] 15 U.S.C. 78q–1(b)(3)(I).

[29] While it was ultimately determined in April 2014 that cash collateral would remain in the escrow deposit program, prior discussions with participating escrow banks reflected the evolution of OCC's decision on this point. For example, the PowerPoint presentation given to banks during June–August 2012 indicated that cash collateral would not be permitted in the escrow deposit program, while the PowerPoint presentation given during April–May 2013, as well as the draft rules distributed to participating escrow banks for comment in July–August 2013, indicated that it *would* be included. A number of current participants in the escrow deposit program use cash, some to a substantial degree, and OCC determined that the use of cash collateral should remain an essential aspect of the escrow deposit program.

In July and August 2013, OCC distributed a draft Participating Escrow Bank Agreement (as described below) and the related proposed OCC Rules to custodian banks along with a request for feedback. Following the receipt of questions and comments, OCC distributed "FAQ" responses to custodian banks.

During September 2013, OCC provided a walkthrough of the functions of its ENCORE[30] system applicable to the enhanced escrow deposit program for custodian banks in order to provide an orientation of such functionality. In connection with the restructured escrow deposit program, clearing members will continue to use ENCORE to view member specific deposits, and custodian banks will use ENCORE to view third-party specific deposits and make escrow deposits consisting of cash. Moreover, OCC sent requests to custodian banks for validation of the DTC pledgor accounts to be used for the restructured escrow deposit program. In October 2013, OCC distributed escrow deposit program eligible securities file details to custodian banks.

In February and March 2014, OCC arranged a series of calls with custodian banks to solicit feedback on a term sheet detailing cash account structures. Following the receipt of questions and comments, OCC distributed "FAQ" responses to custodian banks.

Comments Received From Custodian Banks

As described above, OCC discussed the proposed rule changes to its escrow deposit program with custodian banks several times since 2012. While these discussions were generally informational in nature, custodian banks provided OCC with comments and questions in two instances: The July/August 2013 discussions and the February/March 2014 discussion. The primary focus of the comments in both sets of discussions was the manner in which custodian banks would be required to hold cash under the new escrow rules: In an omnibus structure or in a tri-party structure. The omnibus structure would provide OCC with an account in OCC's name and thereby perfect OCC's right under the UCC to take possession of cash escrow deposits in the event of a clearing member default. This would also eliminate the need for a separate tri-party agreement. However, the omnibus structure was less desirable to custodian banks since all of a custodian bank's OCC escrow deposit program clients' assets would be comingled in a single account. From an operational perspective, a single omnibus account at a custodian bank is easier for OCC to manage since OCC would only need to have "view access" into one account at a custodian bank. On the other hand, custodian banks expressed privacy concerns with respect to several clients having view access into a single account.

Eventually, OCC decided to use a tri-party account structure for cash escrow deposits, with certain controls to alleviate the concerns on both sides. Specifically, custodian banks agreed to facilitate the execution of a form tri-party agreement with each of its clients that participates in OCC's escrow deposit program, which perfects OCC's security interest in cash escrow deposits. Additionally, custodian banks agreed to establish an escrow specific cash account for each client so that OCC does not need to differentiate a client's OCC escrow cash from the client's non-escrow cash. OCC believes that the proposed structure for cash accounts strikes the appropriate balance between OCC's desire for legal certainty as to its right to take possession of cash escrow deposits in the event of a clearing member default, and the operational desire to only have view access to a client's OCC escrow deposit program cash account balance at a custodian bank.

Additional comments OCC received from the July/August 2013 discussions with custodian banks centered on administrative items such as the escrow deposit program documentation structure and the manner in which custodian banks would post escrow deposits in OCC's clearing system, ENCORE. As discussed above, OCC moved the substantial majority of its Amended and Restated On-Line Escrow Deposit Agreement into proposed Rule 610C in order to have the majority of escrow rules in one place. Custodian banks did not express any concerns regarding the operational steps necessary to post an escrow deposit in ENCORE once OCC provided custodian banks with a "walkthrough" of the operational process.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self- regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2016–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2016–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.theocc.com/components/docs/legal/rules_and_bylaws/sr_occ_16_009.pdf.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

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[30] ENCORE is OCC's real-time clearing and settlement system that allows clearing members to, among other things, post and view margin collateral as well as deposits in lieu of margin.

All submissions should refer to File Number SR–OCC–2016–009 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20882 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78685; File No. SR–NYSEMKT–2016–77]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 900.2NY(18A)

August 25, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 12, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 900.2NY(18A). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the filing is to amend Rule 900.2NY(18A), regarding the definition of a "Professional Customer," to align the Exchange's definition with that of competing options exchanges, as discussed below.

The Exchange adopted the definition of a Professional Customer in 2010, after several other options exchanges added this definition.[4] In doing so, the Exchange provided that a Professional Customer would "be treated in the same manner as a Broker/Dealer (or non-Customer) in securities for the purposes" of various Exchange rules "and the Exchange's schedule of fees."[5] Recently, the Exchange amended its Professional Customer definition to align with rules of other markets.[6] However, as part of the harmonization effort for a uniform definition of Professional Customer, the Exchange has determined that other options exchanges do not similarly include reference to their fee schedules in the definition of Professional Customer.[7] Thus, to conform with the rules of other options exchanges, the Exchange proposes to modify Rule 900.2NY(18A) to delete the reference to the Exchange's fee schedule. This change would allow the Exchange, like its competitors, to attract Professional Customer order flow with fees that differentiate Professional Customers from Broker/Dealers.

The Exchange also proposes to make a non-substantive change to clarify the list of rules to which the Professional Customer definition applies, which would add clarity and transparency to Exchange rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[8] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system.

The proposed change would foster cooperation and coordination with persons engaged in facilitating transactions in securities as it would align Exchange rules with that of its competitors, which benefits investors and the public interest. By removing reference to the Exchange's fee schedule from the definition of Professional Customer, the Exchange would, like its competitors, have the ability to attract Professional Customer order flow with fees that differentiate Professional Customers from Broker/Dealers. The proposed rule change would therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by enabling the Exchange to structure its fees for Professional Customers competitively with the fees of other options exchanges.

Further, the proposed changes are not unfairly discriminatory as the modified definition would apply to all similarly-situated ATP Holders that submit orders on behalf of Professional Customers.

Finally, the non-substantive change to the Professional Customer definition would remove impediments to and perfect the mechanisms of a free and open market and a national market system, as it would add clarity and transparency to Exchange rules.

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[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 61818 (March 31, 2010), 75 FR 17457 (April 6, 2010) (SR–NYSEAmex–2010–18). *See also id.,* at note 14 (citing the approval orders of other options exchanges).

[5] *See* Rule 900.2NY(18A).

[6] *See* Securities Exchange Act Release No. 77836 (May 16, 2016), 81 FR 31994 (May 20, 2016) (SR–NYSEMKT–2016–53).

[7] *See, e.g.,* NYSE Arca Rule 6.1A.(4A) (no reference to fee schedule in definition of Professional Customer); Nasdaq OMX PHLX ("PHLX") Rule 1000 (b)(14) (same); Nasdaq Options Market ("NOM") Chapter 1, Sec. 1(a)(48) (same); Bats BZX Exchange, Inc.'s ("BZX") Rule 16.1(a)(46) (same); BOX Options Exchange LLC ("BOX") Rule 100 (a)(50) (same); International Securities Exchange ("ISE") Rule 100(a)(37A) (same); MIAX Options Exchange ("MIAX") Rule 100 (same).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes are pro-competitive as the changes align Exchange rules with that of competing markets and would allow the Exchange to better compete for Professional Customer order flow. The Exchange does not believe that the proposed rule change would impose any burden on intramarket competition because, to the extent the Exchange chooses to adopt fees specific to Professional Customers, such fees would be equal to or less than those charged to broker/dealers and would not be more favorable than fees charged to public customers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6)[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange would be able to propose fees changes related to Professional Customers on September 1, 2016.

The Commission believes waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues. The Exchange's proposal removes the current provision that requires the Exchange to treat Professional Customers and Broker-Dealers in the "same manner" with respect to fees, which will allow the Exchange to separately propose, if it so chooses, to set its fees competitively in order to attract Professional Customer order flow, provided that such competitive fees are consistent with the requirements of the Act and the rules and regulations thereunder. The Commission notes that the Exchange has representated that, to the extent it chooses to adopt fees specific to Professional Customers, such fees would be equal to or less than those charged to broker-dealers and would not be more favorable than fees charged to public customers. Because this proposal does not raise any new or novel issues with respect to the treatment of Professional Customers, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–77 and should be submitted on or before September 21, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20886 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

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[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78680; File No. SR–Phlx–2016–86]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing of Proposed Rule Change to Delete or Amend Outdated Rule Language

August 25, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 12, 2016, NASDAQ PHLX LLC ("Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete or amend outdated rule language contained in Rules 1022, Securities Accounts and Orders of Specialists and Registered Options Traders, 1036, Affiliated Persons of Specialists, and 1037, Floor Reports of Exchanges Options Transactions.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to delete or amend several rules pertaining to the obligations of specialists, as follows.[3]

Rule 1022

Rule 1022 (b) and (c) currently provide that each specialist or Registered Options Trader ("ROT") shall provide certain reports of options and orders in a manner provided by the Exchange. Section (b) requires each specialist or ROT, no later than 10:00 a.m. on the business day following order entry date, to report to the Exchange opening positions and each purchase and sale in each option in which the Specialist or ROT is registered for each account reported pursuant to Rule 1022.[4]

Likewise, Section (c) requires each specialist or ROT, no later than 10:00 a.m. on the business day following order entry date, to report to the Exchange every order entered by the specialist or ROT for the purchase or sale of a security underlying any stock or Exchange-Traded Fund Share options contract traded on the Exchange or a security convertible into or exchangeable for such underlying security as well as opening and closing positions in all such securities held in each account reported pursuant to the rule.[5] The requirements of both Sections (c) and (d) are qualified—the reports are required to be made "in a manner prescribed by the Exchange."

The Exchange is deleting Sections (b) and (c) as obsolete and reserving those sections. The Exchange has previously stated with respect to Rule 1022 that the required reports of activity in each option, as well as activity in the underlying stock, is reviewed daily to insure compliance with Exchange and SEC rules and regulation.[6] However, the Exchange does not require nor does it currently receive the reports specified in those sections because it believes that the burden of filing the reports would outweigh the benefits and it does not believe the reports are necessary to fulfill its regulatory obligations given other sources of information now available to the Exchange. While current Exchange staff is unaware whether a circular was issued advising specialists that they were no longer required to provide the reports required under Rule 1022, the reports have not been required by or received by the Exchange for 15 years or more.

The information referred to in Section (b) is available from The Options Clearing Corporation. Much of the information called for in Section (c) is now available to the Exchange in the ISG Equity Audit Trail known among the exchanges as ECAT.

Rule 1036

Section (a) of Rule 1036, Affiliated Persons of Specialists, currently requires every limited partner, approved person and every party who is affiliated with a specialist member organization to agree, in a stipulation approved by the Exchange, not to violate any Exchange rule or cause a specialist or a specialist member organization to violate these or any other rules relating to specialists. The Exchange currently does not collect such stipulations. The violation of such a stipulation would have provided the Exchange with a separate basis for proceeding against the provider of the stipulation in the event of an Exchange rule violation by that person or by a specialist or specialist member organization. However, the Exchange has determined that the burden of collecting such stipulations would outweigh any benefits and is accordingly proposing to delete and reserve Section (a) of Rule 1036.

Rule 1036(b) provides that no issuer, or parent or subsidiary thereof, or any officer, director or 10% stockholder thereof, may become an approved person in a specialist member organization whose members are registered in a security of that issuer. Rule 1036(b) however applies only to *options* trading on the Exchange. Therefore, the Exchange is amending Rule 1036(b) to refer to members who are registered in options overlying a security of that issuer.[7]

Rule 1037

Rule 1037, Floor Reports of Exchanges Options Transactions, provides for a specialist's liability for missed orders on the book. Under the rule a specialist was liable for any loss sustained for orders entrusted to him which should have been executed, and for which he should have sent an execution report, when the specialist was made aware of the error by 9:30 on the business day following the submission of the order.[8] Rule 1037 is being deleted as obsolete and reserved. Due to the migration of the Exchange to a new electronic trading system ("Phlx XL II") in 2009, missed orders by Specialists no longer occur because Specialists no longer handle orders for other market participants in their capacity as Specialists.[9] Missed orders cannot occur because orders are not held or guaranteed by Specialists, who now trade only for their own accounts in that capacity. The deletion of Rule 1037 should prevent confusion that may result from having obsolete rules in the Exchange's rulebook.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A "specialist" is an Exchange member who is registered as an options specialist pursuant to Exchange Rule 1020(a). Specialists are subject to quoting and registration obligations set forth in Rules 1014(b), 1020 and 1080.02.

[4] The report is required to designate the time and type of tick at which such transaction was effected.

[5] The report pertaining to orders must include the terms of each order, identification of the brokerage firms through which the orders were entered, the times of entry or cancellation, the times reports of executions were received and, if all or part of the order was executed, the quantity and execution price.

[6] *See* Securities Exchange Act Release No. 19940 (July 1, 1983), 48 FR 31950 (July 12, 1983).

[7] The Exchange is also correcting the rule by changing the word "who" to "whose".

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by deleting obsolete provisions and generally providing clarity to the rules.

Rule 1022

The amendments to Rule 1022 are consistent with the Act because they delete requirements that specialists and ROTs provide reports which the Exchange no longer needs in order to fulfill its regulatory responsibilities. The elimination of the requirements reduces an unnecessary burden on ROTs and specialists, which therefore removes an impediment to a free and open market and a national market system.

Rule 1036

The amendments to Rule 1036 are consistent with the Act because they clarify that Rule 1036(b) applies to option specialist member organizations. They also eliminate requirements that certain affiliates of specialists or related persons provide stipulations the collection of which the Exchange believes to be a burden that is not outweighed by its benefits. The elimination of the requirement reduces an unnecessary burden on the Exchange, which therefore removes an impediment to a free and open market and a national market system.

Rule 1037

The deletion of Rule 1037 is consistent with the Act because this rule language is operationally obsolete, as explained above; moreover, having clear and up-to-date rules should promote just and equitable principles of trade on the Exchange. The proposal should result in a more accurate and understandable rule book, particularly for Exchange specialists who no longer operate a book or handle orders for accounts other than their own.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposal raises neither intra-market nor inter-market competition issues. The proposal deletes or amends obsolete or unnecessary provisions or clarifies rules and therefore does not impact how the market operates today.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–86 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–86. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–Phlx–2016–86 and should be submitted on or before September 21, 2016.

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[8] In a May 17, 1991 amendment to SR-Phlx-91-21, the Exchange amended the introductory language of Rule 1037 by replacing "12:00 noon" with "9:30 a.m.". The same change was also made to Commentary .03. It appears that although the change to Commentary .03 was then carried over into the rulebook, the same change to the introductory language was inadvertently overlooked and thus not reflected in the rulebook. *See* Securities Exchange Act Release No. 32695 (July 29, 1993), 58 FR 41821 (August 5, 1993).

[9] In May 2009, the Exchange enhanced the options trading system and adopted corresponding rules referring to it as "Phlx XL II." See Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR-Phlx-2009-32). Thereafter, the Exchange submitted a number of filings updating various rules and deleting obsolete provisions. See Securities Exchange Act Release Nos. 61397 (January 22, 2010), 75 FR 4893 (January 29, 2010) (SR-Phlx-2010-07); 63036 (October 4, 2010), 75 FR 62621 (October 12, 2010) (SR-Phlx-2010-131); and 67469 (July 19, 2012), 77 FR 43633 (July 25, 2012) (SR-Phlx-2012-92).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–20893 Filed 8–30–16; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 9697]

Culturally Significant Objects Imported for Exhibition Determinations: "God's Servant First: The Life and Legacy of Thomas More" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "God's Servant First: The Life and Legacy of Thomas More," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Saint John Paul II National Shrine, Washington, District of Columbia, from on about September 16, 2016, until on or about March 31, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: August 25, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–20966 Filed 8–30–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9696]

Culturally Significant Objects Imported for Exhibition Determinations: "Medardo Rosso: Experiments in Light and Form" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 257 of April 15, 2003, I hereby determine that the objects to be included in the exhibition "Medardo Rosso: Experiments in Light and Form," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Pulitzer Arts Foundation, St. Louis, Missouri, from on or about November 11, 2016, until on or about May 13, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: August 23, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–20957 Filed 8–30–16; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1245X]

Michigan Southern Railroad Company, d/b/a Napoleon, Defiance & Western Railway—Discontinuance of Service Exemption—in Henry County, Ohio

On August 11, 2016, Michigan Southern Railroad Company, d/b/a Napoleon, Defiance & Western Railway (NDW) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue rail service over approximately 5.43 miles of rail line between milepost TN 28.0, near Liberty Center, Ohio, and milepost TN 33.43, near Napoleon, Ohio, in Henry County, Ohio. The line traverses U.S. Postal Service Zip Codes 43545 and 43532, and includes the station of Liberty Center, which NDW states will be discontinued.

NDW states that the line does not contain any federally granted rights-of-way. Any documentation in NDW's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad–Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 29, 2016.

Because this is a discontinuance proceeding and not an abandonment proceeding, trail use/rail banking and public use conditions are not appropriate. Because there will be environmental review during abandonment, this discontinuance does not require an environmental review.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) to subsidize continued rail service will be due no later than December 9, 2016, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner. Each offer must be accompanied by a $1,600 filing fee. *See* 49 CFR 1002.2(f)(25).

All filings in response to this notice must refer to Docket No. AB 1245X and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave., NW., Suite 300, Washington, DC 20037. Replies to the petition are due on or before September 20, 2016.

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[12] 17 CFR 200.30–3(a)(12).

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR pt. 1152. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: August 24, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Rena Laws-Byrum,

Clearance Clerk.

[FR Doc. 2016–20744 Filed 8–30–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eighty-Sixth SC–147 Traffic Collision & Avoidance Committee Plenary

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Eighty-sixth SC–147 Traffic Collision & Avoidance Committee Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Eighty-Sixth SC–147 Traffic Collision & Avoidance Committee Plenary.

DATES: The meeting will be held September 26–29, 2016 09:00 a.m.—04:30 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Al Secen at *asecen@rtca.org* or 202–330–0647, or The RTCA Secretariat, 1150 18th Street, NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Eighty-Sixth SC–147 Traffic Collision & Avoidance Committee Plenary. The agenda will include the following:

Monday September 26

Combined Surveillance Group Leadership Meeting

Working group breakout meetings

Tuesday September 27

Working group breakout meetings

Wednesday September 28

Working group breakout meetings

Thursday September 29

Plenary Meeting and Agenda

1. Opening Plenary Session
   a. Chairmen's Opening Remarks/Introductions
   b. Approval of Minutes from 85th meeting of SC–147
   c. Approval of Agenda
2. WG75 Status/European Activities
3. Working Group Reports
   a. Report from Surveillance and Tracking Working Group (SWG)
   b. Report from Threat Working Group TWG
   c. Report from Safety Sub-group
4. Working Group Reports Continued
   a. Report from Combined Surveillance Group (CSG)
   b. Report from Xo Sub-group
   c. Report from Xu Sub-group
   d. Report from Operations Working Group (OWG)
5. MOPS Schedule Review

Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on August 25, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–20909 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Eighteenth Meeting of SC–227 Navigation Information on Electronic Maps

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Eighteenth Meeting of the SC–227 Navigation Information on Electronic Maps.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Eighteenth Meeting of SC–227 Navigation Information on Electronic Maps.

DATES: The meeting will be held September 20–22, 2016, 9:00 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at: 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Jennifer Iversen at *jiversen@rtca.org* or (202) 330–0662, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Eighteenth Meeting of the SC–227, Navigation Information on Electronic Maps. The agenda will include the following:

September 20–22, 2016, 9:00 a.m. to 4:30 p.m.

Plenary—Tuesday, September 20, 2016, 09:00–10:00

1. Welcome and Administrative Remarks
2. Introduction
3. Review of Minutes from Meeting 17.
4. Agenda Overview
   a. Schedule
   b. New Business
   c. SC227 Terms of Reference Updates
5. Review and discussion of MOPS issues and change proposals.

Closing Plenary—Thursday, September 22, 2016, 10:45–Noon

1. Working Group 2 Progress Report/Summary
2. Other Business
3. Date of Next Meeting
4. Adjourn

Working Group of a Whole will take place at all other meeting times outside of stated Plenary sessions.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 26, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–20986 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2016–0022]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by October 31, 2016.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2016–0022 by any of the following methods:

Web site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Derek Constable, 202–366–4606, or Shay Burrows, 202–366–4675, Office of Bridges and Structures, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Information Collection for the FAST Act Section 1422 Study on Performance of Bridges.

Background: Section 1422 of the Fixing America's Surface Transportation (FAST) Act of 2015 calls for the FHWA to commission the Transportation Research Board to conduct a study on the performance of bridges funded by the Innovative Bridge Research and Construction (IBRC) program as provided under section 503(b) of Title 23, United States Code, and in effect on the day before the date of enactment of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) of 2005. The IBRC program was originated by the Transportation Equity Act for the 21st Century (TEA–21) of 1998 with the purpose of demonstrating the application of innovative material technology in the construction of bridges and other structures. Seven program goals were identified in TEA–21. SAFTEA–LU continued the program, but amended the program name, purpose, and goals. The program was then discontinued with the passage of the Moving Ahead for Progress in the 21st Century Act (MAP–21) of 2012. The FAST Act directs FHWA to commission the Transportation Research Board to conduct a study on the performance of bridges that received funding under the IBRC program. The IBRC program awarded funds from Federal fiscal year 1998 through 2005 allocations to help defray costs on approximately 445 projects.

The study will include an analysis of the performance of bridges that received funding under the IBRC program in meeting the program goals. The study will include an analysis of the utility, compared to conventional materials and technologies, of each of the innovative materials and technologies used in projects for bridges under the program in meeting the present and future needs of the United States in 2015 and in the future for a sustainable and low lifecycle cost transportation system. The study will make recommendations to Congress on how the installed and lifecycle costs of bridges could be reduced through the use of innovative materials and technologies, including, as appropriate, any changes in the design and construction of bridges needed to maximize the cost reductions. The study will include a summary of any additional research that may be needed to further evaluate innovative approaches to reducing the installed and lifecycle costs of highway bridges.

By separate action the FHWA will be providing public notice of the study proposal with opportunity for comment.

The conduct of this study will require that each State, that received funds under the IBRC program, provide to the Transportation Research Board any relevant information and data needed to carry out the study. Recipients of IBRC funding may be asked to provide information and data by interview, survey, and/or release of records. Interviews and surveys may be required to determine which projects to focus investigations and to gather relevant background, cost, and performance information. Records required may include data, documents, and reports associated with design, construction, in-service inspection, maintenance, evaluation, monitoring, and other relevant phases or activities. The study will make use of the IBRC project information previously supplied to the FHWA, but this information is generally insufficient to accomplish the study objectives.

Respondents: Approximately the 50 States, District of Columbia, and Puerto Rico. The respondents may need to provide information and data for multiple projects if awarded IBRC program funding for multiple projects. There are an estimated 445 projects requiring different levels of information collection.

Frequency: This is a one-time study.

Estimated Average Burden per Project: On average approximately 5.25 hours per project.

Estimated Total Annual Burden Hours: Approximately 2,336 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Michael Howell,

Information Collection Officer.

[FR Doc. 2016–20931 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0206]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 12 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce.

DATES: Comments must be received on or before September 30, 2016. All comments will be investigated by FMCSA. The exemptions will be issued the day after the comment period closes.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2016–0206 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." FMCSA can renew exemptions at the end of each 2-year period. The 12 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

Timothy D. Beaulier

Mr. Beaulier, 58, has had a macular scar in his right eye due to a traumatic incident in 1971. The visual acuity in his right eye is light perception, and in his left eye, 20/20. Following an examination in 2016, his optometrist stated, "Tim does well as a monocular patient. I feel he will have no issues on the roadway based on visual demands. I do not see any issue with Tim Beaulier's ability to safely operate a commercial vehicle at this time." Mr. Beaulier reported that he has driven straight trucks for 30 years, accumulating 15,000 miles and tractor-trailer combinations for 14 years, accumulating 218,400 miles. He holds a Class CA CDL from Michigan. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Earl D. Edland

Mr. Edland, 71, has complete loss of vision in his right eye since childhood. The visual acuity in his right eye is no light perception, and in his left eye, 20/25. Following an examination in 2015, his ophthalmologist stated, "His visual status has been stable for many years . . . Mr. Edland appears to be functioning well and it is my opinion that he is capable of operating a commercial motor vehicle in traffic." Mr. Eldand reported that he has driven straight trucks for 50 years, accumulating 1.3 million miles. He holds a Class B CDL from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

David M. Field

Mr. Field, 50, has had amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/400, and in his left eye, 20/15. Following an examination in 2016, his ophthalmologist stated, "Where he has been functioning successfully with excellent central and peripheral vision under binocular conditions, it is my opinion that he has more than sufficient vision to continue to perform the driving tasks required to operate a commercial vehicle." Mr. Field reported that he has driven straight trucks for 30 years, accumulating 1.5 million miles and tractor-trailer combinations for 30 years, accumulating 1.5 million miles. He holds a Class AMC CDL from New Hampshire. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Jerry D. Gartman

Mr. Gartman, 60, has had amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2016, his optometrist stated, "In my medical opinion, Mr. Gartman has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Gartman reported that he has driven straight trucks for 3 years, accumulating 90,000 miles and tractor-trailer combinations for 14 years, accumulating 700,000 miles. He holds a Class AM CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

William I. Inskeep

Mr. Inskeep, 57, has glaucoma in his right eye due to a traumatic incident in 2009. The visual acuity in his right eye is 20/70, and in his left eye, 20/15. Following an examination in 2016, his optometrist stated, ''Mr. Inskeep has been able to drive a commercial vehicle over the years and could continue to do so since his glaucoma is stable and unchanged since 2009.'' Mr. Inskeep reported that he has driven straight trucks for 27 years, accumulating 810,000 miles, and tractor-trailer combinations for 3 years, accumulating 45,000 miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Spencer B. Jacobs

Mr. Jacobs, 41, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/70. Following an examination in 2016, his optometrist stated, ''It is my expert opinion that Spencer Jacobs has sufficient vision to operate a commercial vehicle.'' Mr. Jacobs reported that he has driven tractor-trailer combinations for 3 years, accumulating 22,500 miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Edison Joe

Mr. Joe, 62, has had anisometropia and amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/40, and in his left eye, 20/20. Following an examination in 2016, his optometrist stated, ''From a vision standpoint only, Mr. Joe has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Joe reported that he has driven straight trucks for 10 years, accumulating 260,000 miles. He holds an operator's license from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Duane A. McCord

Mr. McCord, 49, has a prosthesis in his right eye due to a traumatic incident in childhood. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2016, his optometrist stated, ''Based on all of the findings, I have determined that Mr. McCord does have sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. McCord reported that he has driven straight trucks for 10 years, accumulating 500,000 miles. He holds an operator's license from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Odilio Monterroso De Leon

Mr. Monterroso De Leon, 44, has had a prosthetic in his left eye due to a traumatic incident in birth. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2016, his optometrist stated, ''I certify that in my medical opinion, Mr. Monterroso has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Monterroso De Leon reported that he has driven straight trucks for 15 years, accumulating 1.88 million miles. He holds an operator's license from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James M. Moore

Mr. Moore, 74, has a prosthetic in his left eye due to a traumatic incident in 1976. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2016, his optometrist stated, ''I certify from the above qualifications that Mr. Moore has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Moore reported that he has driven tractor-trailer combinations for 30 years, accumulating 3.12 million miles. He holds a Class A CDL from Mississippi. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Raymond White

Mr. White, 58, has a retinal detachment in his right eye since childhood. The visual acuity in his right eye is counting fingers, and in his left eye, 20/20. Following an examination in 2015, his ophthalmologist stated, ''I would consider that Mr. White has adequate vision to perform driving tests [sic] and to operate a commercial vehicle.'' Mr. White reported that he has driven tractor-trailer combinations for 38 years, accumulating 4.94 million miles. He holds a Class A CDL from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Brian C. Wittenburg

Mr. Wittenburg, 43, had a cerebrovascular accident in his right eye in 2006. The visual acuity in his right eye is counting fingers, and in his left eye, 20/20. Following an examination in 2016, his ophthalmologist stated, ''Mr. Wittenburg has sufficient vision to continue to operate a commercial vehicle.'' Mr. Wittenburg reported that he has driven straight trucks for 20 years, accumulating 500,000 miles. He holds an operator's license from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

III. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and put the docket number FMCSA–2016–0206 in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and insert the docket number FMCSA–2016–0206 in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: August 19, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–20932 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0344]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 30 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions were granted January 8, 2016. The exemptions expire on January 8, 2018.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On December 8, 2015, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (80 FR 76345). That notice listed 30 applicants' case histories. The 30 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 30 applications on their merits and made a determination to grant exemptions to each of them.

III. Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

> A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 30 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, anisometropic amblyopia, chorioretinal scar, chronic rhegmatagenous, complete loss of vision, corneal scar, enucleation, glaucoma, hyperopic astigmatism, macular degeneration, macular hole, macular pucker, ocular damage, optic atrophy, optic nerve atrophy, optic neuritis, prosthetic eye, retinal detachment, retinal hole, retinal scar, and toxoplasmosis. In most cases, their eye conditions were not recently developed. Fourteen of the applicants were either born with their vision impairments or have had them since childhood.

The 16 individuals that sustained their vision conditions as adults have had it for a range of 3 to 21 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 30 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision in careers ranging for 3 to 56 years. In the past three years, no drivers were involved in crashes, and 4 drivers were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the December 8, 2015 notice (80 FR 76345).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., "Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process," Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 30 applicants, no drivers were involved in crashes, and 4 drivers were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 30 applicants listed in the notice of December 8, 2015 (80 FR 76345).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 30 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

V. Discussion of Comments

FMCSA received one comment in this proceeding. Johnny Campbell, having known Franklin Tso professionally for 25 years, is in favor of granting Mr. Tso and exemption from the vision standard.

IV. Conclusion

Based upon its evaluation of the 30 exemption applications, FMCSA exempts the following drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)):

Thomas G. Ashbrook (NY)
Howard D. Barton (IN)
Bryan Borrowman (UT)
George R. Cornell (OH)
Bruce J. Dowd (CT)
Raul A. Gonzalez (CA)
Calvin N. Gregory, Jr. (MD)
Thomas E. Gross (PA)
Ethan A. Hale (KY)
Steven G. Hall (NC)
Jason F. Huddleston (TX)
David A. Luke (NE)
Raymond J. Mannarino (NY)
Samuel T. Mazza, Jr. (CT)
Ralph S. Miller (VA)
John M. Moore (PA)
Samuel M. Mosman (WA)
Josh D. Nichols (IL)
John P. Pitts (AZ)
Alexander L. Resh (PA)
August Roberts, Jr. (NC)
Phillip D. Satterfield (GA)
Fred Schmidt (IL)
Robert L. Simpson (NC)
Franklin Tso (NM)
Keith D. Turnbow (MO)
James L. Urbach (PA)
Eric C. Weidley (PA)
Jackie G. Wells (VA)
Charles T. Whitehead (NC)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: August 19, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–20925 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

[Docket No. DOT–MARAD–2016–0087]

Request for Comments of a Previously Approved Information Collection

AGENCY: Maritime Administration (MARAD).

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on June 2, 2016 (**Federal Register** 35440, Vol. 81, No.106).

DATES: Comments must be submitted on or before September 30, 2016.

FOR FURTHER INFORMATION CONTACT: Barbara Jackson, 202–366–0615, Maritime Administration, Department of Transportation, 1200 New Jersey Avenue SE., W26–494, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Maritime Administration Service Delivery.

OMB Control Number: 2133–0546.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 15.

Estimated Number of Respondents: 5900.

Estimated Number of Responses: 5900.

Annual Estimated Total Annual Burden Hours: 1758.

Frequency of Response: Once.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

By Order of the Maritime Administrator.

Dated: August 23, 2016.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2016–20872 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Modification of Special Permit.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before September 30, 2016.

ADDRESS COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC, or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on August 19, 2016.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
10704–M		Boost Oxygen, LLC	173.302a(a)(1)	To modify the special permit to authorize an additional packaging.
11110–M		United Parcel Service Co	175.75, 175.75	To modify the special permit to authorize certain Class 8 hazardous materials which have no assigned packing group to be transported under the terms of the special permit.
13307–M		United Phosphorus Inc	172.500, 172.504, 172.504, 172.504, 172.504, 172.504, 172.506.	To modify the special permit to authorize a new hazmat and new packaging.
13996–M		TK Holdings Inc		To update the permit to bring it in line with regulatory changes made in HM–254 and HM–215M.
14175–M		Linde Gas North America LLC.	180.209(b)	To authorize an additional hazmat to be carried in the permitted cylinders.
15869–M		Mercedes-Benz USA, LLC.		To modify the special permit to authorize the transportation of production run lithium ion batteries weighing over 35 kg by cargo aircraft.

[FR Doc. 2016–20588 Filed 8–30–16; 8:45 am]

BILLING CODE 4909–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before September 30, 2016.

ADDRESS COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on August 15, 2016.

Donald Burger,

Chief, Office of the Special Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
SPECIAL PERMITS DATA				
20279–N		Aladdin Fire Protection	180.207(d)(1)	To authorize the use of hydrostatic volumetric expansion testing in lieu of ultrasonic emissions testing for UN ISO 9809ndash;2 cylinders exceeding 950 MPa. (modes 1, 2, 3, 4, 5)
20283–N		LG CHEM	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding the 35 Kg maximum weight authorized for transportation by cargo aircraft. (mode 4)
20285–N		Kinross EMS	173.196	To authorize the transportation of Category A infectious substances in non-DOT specification packaging following the transportation of a patient diagnosed with an infectious disease. (mode 1)
20287–N		Linde LLC	172.203(a), 172.302(c), 180.205(c), 180.209(a), 180.209(b), 180.209(b)(iv).	To authorize certain cylinders to be ultrasonically tested at least once every ten years. (modes 1, 2, 3)
20288–N		U.S. Army CE–LCMC	175.10 (a)(18)(ii)	To authorize the transportation of lithium ion batteries in carry-on luggage with a Watt-hour rating greater than 100 Wh. (mode 5)
20289–N		FDC Composites Inc	173.242	To authorize the manufacture, mark, sale, and use of non-DOT specification glass fiber reinforced plastic (GFRP) cargo tank conforming with all applicable requirements for DOT specification 412/407 cargo tanks, except as specified herein. (mode 1)
20290–N		LG CHEM	172.101(j)	To authorize the transportation of lithium ion batteries exceed the 35 kg weight limitation on cargo aircraft. (mode 4)
20291–N		Board of Regents of the University of Nebraska.	171.2(k)	To authorize the transportation in commerce of packages of non-hazardous material identified as Category A infectious substances for purposes of shipping and packaging drills. (mode 1)
20292–N		Nuance Systems LLC	173.302(a), 173.181, 178.35(b), 178.35(b)(1), 178.35(c), 178.50(a), 178.50(d)(2).	To authorize the manufacture, marking sale and use of a non-DOT specification cylinder for the transportation of pyrophoric materials. (modes 1, 2, 3)
20293–N		LG CHEM	173.185(a)	To authorize the transportation in commerce of prototype lithium ion batteries by cargo-only aircraft. (mode 4)
20294–N		The Dow Chemical Company.	172.23(a), 172.302(c), 180.605(h)(3).	To authorize a 5 year periodic pressure test on UN portable tanks used in the transport of a Division 4.3 material to be performed with mineral oil rather than with water. (modes 1, 2, 3)
20297–N		Codysales Inc	173.302a(b), 172.203(a), 172.301(c), 180.205.	To authorize the use of certain DOT specification 3A, 3AA, 3AL, SP9001, SP9370, SP9421, SP9706, SP9791, SP9909, SP10047, SP10869, SP11692, SP12440 cylinders used for the transportation in commerce of certain compressed gases, when retested by a 100% ultrasonic examination in lieu of the internal visual and the hydrostatic retest required in 49 CFR 180.205. (modes 1,2,3,4,5)
20301–N		Tesla Motors, Inc	173.185(a)	To authorize the transportation in commerce of prototype lithium ion batteries via cargo aircraft. (mode 4)
20302–N		Tesla Motors, Inc	173.220(d)	To authorize the transportation in commerce of vehicles containing prototype lithium ion batteries via cargo-only aircraft and cargo vessel. (modes 3, 4)
20303–N		Faraday & Future Inc	173.185(a), 173.220(d)	To authorize the transportation of prototype and low production lithium ion batteries, and vehicles containing these batteries, via cargo-only aircraft. (mode 4)
20305–N		Atlas Air, Inc	173.27(b)(2), 173.27(b)(3), 172.204(c)(3), 175.30(a)(1).	To authorize the transportation in commerce of certain explosives by cargo aircraft only, which are otherwise forbidden. (mode 4)

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
20306–N	....	Avantor Performance Materials International, Inc..	173.158(e)	To authorize the transportation in commerce of nitric acid in fiberboard outer packagings without the use of intermediate packaging or absorbent material. (modes 1, 2, 3)

[FR Doc. 2016–20592 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Delayed Special Permit Applications

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), PHMSA is publishing the following list of special permit applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Special Permits and Approvals, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

Key to "Reason for Delay"

1. Awaiting additional information from applicant
2. Extensive public comment under review
3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis
4. Staff review delayed by other priority issues or volume of special permit applications

Meaning of Application Number Suffixes

N—New application
M—Modification request
R—Renewal Request
P—Party to Exemption Request

Issued in Washington, DC, on August 19, 2016.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Applicant	Reason for delay	Estimated date of completion
	MODIFICATION TO SPECIAL PERMITS		
15537–M	Alaska Pacific Powder Company, Watkins, CO	4	08–31–2016
13192–M	Thomas Gray & Associates, Inc., Orange, CA	4	08–31–2016
13173–M	Luxfer Canada Limited, Calgary, AB	4	08–31–2016
15610–M	TechKnowServ Corp., State College, PA	4	08–31–2016
	New Special Permit Applications		
16620–N	Westeel Canada Inc., Winnipeg, Canada	4	08–31–2016
16524–N	Quantum Fuel Systems Technologies Worldwide, Inc., Lake Forest, CA	4	08–31–2016
15767–N	Union Pacific Railroad Company, Omaha, NE	3	08–31–2016
	Party to Special Permits Application		
12412–P	Seaco Technologies, Inc., Bakersfield, CA	4	08–31–2016

[FR Doc. 2016–20589 Filed 8–30–16; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the limitation on reduction in income tax liability incurred to the Virgin Islands (§ 1.934–1).

DATES: Written comments should be received on or before October 31, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Limitation on Reduction in Income Tax Liability Incurred to the Virgin Islands.

OMB Number: 1545–0782.

Regulation Project Number: TD 6629.

Abstract: Internal Revenue Code section 934(a) (1954 code) provides that the tax liability incurred to the Virgin Islands shall not be reduced except to the extent provided in Code section 934(b) and (c). Taxpayers applying for tax rebates or subsidies under section 934 of the 1954 Code must provide certain information in order to obtain these benefits.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Individuals or households and business or other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Respondent/Reporting: 12 minutes.

Estimated Time per Respondent/Record-Keeping: 10 minutes.

Estimated Total Annual Reporting Burden Hours: 100.

Estimated Total Annual Record-Keeping Burden Hours: 85.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 23. 2016.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2016–20983 Filed 8–30–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Special rules for certain medical uses of chemicals that deplete the ozone layer.

DATES: Written comments should be received on or before October 31, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Allan Hopkins, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Chemicals That Deplete the Ozone Layer.

OMB Number: 1545–1361.

Regulation Project Number: TD 8662.

Abstract: These regulations impose reporting and recordkeeping requirements necessary to implement Internal Revenue Code sections 4681 and 4682 relating to the tax on chemicals that deplete the ozone layer and on products containing such chemicals. The regulation affects manufacturers and importers of ozone-depleting chemicals, manufacturers of rigid foam insulation, and importers of products containing or manufactured with ozone-depleting chemicals manufacture, import, export, sell, or use ODCs.

In addition, the regulation affects persons, other than manufacturers and importers of ozone-depleting chemicals, holding such chemicals for sale or for use in further manufacture on January 1, 1990, and on subsequent tax-increase dates.

This regulation provides reporting and recordkeeping rules relating to taxes imposed on exports of ozone-depleting chemicals (ODCs), taxes imposed on ODCs used as medical sterilants or propellants in metered-dose inhalers, and floor stocks taxes on ODCs. The rules affect persons who

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 151,598.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Reporting Burden Hours: 75140.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 23, 2016.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2016–20988 Filed 8–30–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8038–B

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8038–B, Information Return for Build America Bonds and Recovery Zone Economic Development Bonds.

DATES: Written comments should be received on or before October 31, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of notice should be directed to Allan Hopkins at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet, at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Information Return for Build America Bonds and Recovery Zone Economic Development Bonds.

OMB Number: 1545–2161.

Notice Number: Form 8038–B.

Abstract: Form 8038–B has been developed to assist issuers of the new types of Build America and Recovery Zone Economic Development Bonds enacted under the American Recovery and Reinvestment Act of 2009 to capture information required by IRC section 149(e).

Current Actions: Extension of currently approved collection. There are no changes being made to this collection at this time.

Type of Review: Extension of currently approved collection.

Affected Public: Not for profit institutions.

Estimated Number of Respondents: 5,880.

Estimated Average Time per Respondent: 19 hrs., 19 mins.

Estimated Total Annual Burden Hours: 113,661 hrs.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 23, 2016.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2016–20984 Filed 8–30–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 26, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before September 30, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–0159.

Type of Review: Extension of a currently approved collection.

Title: Annual Return To Report Transactions With Foreign Trusts and Receipt of Certain Foreign Gifts.

Form: Form 3520.

Abstract: U.S. persons (and executors of estates of U.S. decedents) file this form to report: Certain transactions with foreign trusts; ownership of foreign trusts under the rules of sections Internal Revenue Code 671 through 679; and receipt of certain large gifts or bequests from certain foreign persons.

Estimated Total Annual Burden Hours: 71,742.

OMB Control Number: 1545–0213.

Type of Review: Extension of a currently approved collection.

Title: Form 5578—Annual Certification of Racial Nondiscrimination for a Private School Exempt From Federal Income Tax.

Form: Form 5578.

Abstract: Form 5578 may be used by organizations that operate tax-exempt private schools to provide the Internal Revenue Service with the annual certification of racial nondiscrimination required by Rev. Proc. 75–50.

Estimated Total Annual Burden Hours: 3,730.

OMB Control Number: 1545–0742.

Type of Review: Extension of a currently approved collection.

Title: EE–111–80 (TD 8019—Final) Public Inspection of Exempt Organization Return.

Abstract: Section 6104(b) authorizes the Service to make available to the public the returns required to be filed by exempt organizations. The information requested in Treasury Reg. section 301.6104(b)–1(b)(4) is necessary in order for the Service not to disclose confidential business information furnished by businesses which contribute to exempt black lung trusts.

Estimated Total Annual Burden Hours: 22.

OMB Control Number: 1545–0939.

Type of Review: Extension of a currently approved collection.

Title: Form 8404—Interest Charge on DISC-Related Deferred Tax Liability.

Form: Form 8404.

Abstract: Shareholders of Interest Charge Domestic International Sales Corporations (IC–DISCs) use Form 8404 to figure and report an interest charge on their DISC-related deferred tax liability. The interest charge is required by Internal Revenue Code section 995(f). IRS uses the form to determine whether the shareholder has correctly figured and paid the interest charge on a timely basis.

Estimated Total Annual Burden Hours: 15,580.

OMB Control Number: 1545–1452.

Type of Review: Extension of a currently approved collection.

Title: FI–43–94 (TD 8649—Final) Regulations Under Section 1258 of the Internal Revenue Code of 1986; Netting Rule for Certain Conversion Transactions.

Abstract: Section 1258 recharacterizes capital gains from conversion transactions as ordinary income to the extent of the time value element. This regulation provides that certain gains and losses may be netted for purposes of determining the amount of gain recharacterized.

Estimated Total Annual Burden Hours: 5,000.

OMB Control Number: 1545–1507.

Type of Review: Extension of a currently approved collection.

Title: Treatment of Shareholders of Certain Passive Investment Companies.

Estimated Total Annual Burden Hours: 100,000.

OMB Control Number: 1545–1551.

Type of Review: Revision of a currently approved collection.

Title: Changes in Methods of Accounting (RP 2016–29).

Abstract: This revenue procedure (2016–29) provides the procedures by which a taxpayer may obtain automatic consent for a change in method of accounting described in the appendix of Revenue Procedure 2011–14.

Estimated Total Annual Burden Hours: 30,580.

OMB Control Number: 1545–1556.

Type of Review: Extension of a currently approved collection.

Title: TD 8786—Source of Income From Sales of Inventory Partly From Sources Within a Possession of the U.S.; Also, Source of Income Derived From Certain Purchases From a Corp. Electing Sec. 936.

Estimated Total Annual Burden Hours: 500.

OMB Control Number: 1545–1559.

Type of Review: Extension of a currently approved collection.

Title: Revenue Procedures 98–46 and 97–44, LIFO Conformity Requirement.

Abstract: Rev. Proc. 98–46 extended the relief in Rev. Proc. 97–44 to medium and heavy truck dealers.

Estimated Total Annual Burden Hours: 100,000.

OMB Control Number: 1545–1704.

Type of Review: Revision of a currently approved collection.

Title: Change in Minimum Funding Method (Rev. Proc. 2016–XX).

Abstract: This revenue procedure provides a mechanism whereby a plan sponsor or plan administrator may obtain a determination from the Internal Revenue Service that its proposed change in the method of funding its pension plan(s) meets the standards of sections 412 of the Internal Revenue Code. This updates Rev. Proc. 2000–41 based on changes in law primarily due to the Pension Protection Act of 2006.

Estimated Total Annual Burden Hours: 234.

OMB Control Number: 1545–1706.

Type of Review: Extension of a currently approved collection.

Title: TD 9315—Section 1503(d) Closing Agreement Requests.

Abstract: Revenue Procedure 2000–42 informs taxpayers of the information they must submit to request a closing agreement under Reg. S1.1503–2(g)(2)(iv)(B)(2)(i) to prevent the recapture of dual consolidated losses (DCLs) upon the occurrence of certain triggering events.

TD 9315 contains final regulations under section 1503(d) of the Internal Revenue Code (Code) regarding dual consolidated losses. Section 1503(d) generally provides that a dual consolidated loss of a dual resident corporation cannot reduce the taxable income of any other member of the affiliated group unless, to the extent provided in regulations, the loss does not offset the income of any foreign corporation. Similar rules apply to losses of separate units of domestic corporations. These final regulations address various dual consolidated loss issues, including exceptions to the general prohibition against using a dual consolidated loss to reduce the taxable income of any other member of the affiliated group.

Estimated Total Annual Burden Hours: 2,000.

OMB Control Number: 1545–2156.

Type of Review: Revision of a currently approved collection.

Title: Revenue Procedure 2010–13, Disclosure of Activities Grouped under Section 469.

Abstract: This revenue procedure requires taxpayers to report to the Internal Revenue Service their groupings and regroupings of activities and the addition of specific activities within their existing groupings of activities for purposes of section 469 of the Internal Revenue Code and § 1.469–4 of the Income Tax Regulations.

Estimated Total Annual Burden Hours: 36,000.

OMB Control Number: 1545–2247.

Type of Review: Extension of a currently approved collection.

Title: TD 9633—Limitations on Duplication of Net Built-in Losses.

Abstract: These regulations will provide guidance for applying 26 U.S.C. 362(e)(2), relating to the limitation on transfer of built-in losses.

Estimated Total Annual Burden Hours: 75,000.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–20993 Filed 8–30–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 26, 2016.

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Departmental Offices

OMB Control Number: 1505–0216.

Type of Review: Revision of a currently approved collection.

Title: Troubled Asset Relief Program—Making Home Affordable Participants.

Abstract: Authorized under the Emergency Economic Stabilization Act (EESA) of 2008 (Pub. L. 110–343), the Department of the Treasury has implemented several aspects of the Troubled Asset Relief Program (TARP). Among these components is a voluntary foreclosure prevention program—the Making Home Affordable (MHA) program, under which the Department uses TARP capital to lower the mortgage payments of qualifying borrowers. The Treasury does this through agreements with mortgage servicers (Servicer Participation Agreements, or SPAs) to modify loans on their systems. Data is collected from servicers to ensure that the servicers can be paid for the loan modifications that they undertake, check for compliance, and report out on the effectiveness of the program.

Estimated Total Annual Burden Hours: 104,880.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–20958 Filed 8–30–16; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 26, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

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FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Control Number: 1513–0110.

Type of Review: Extension of a currently approved collection.

Title: Recordkeeping for Tobacco Products Removed in Bond from a Manufacturer's Premises for Experimental Purposes—27 CFR 40.232(e).

Abstract: The Internal Revenue Code at 26 U.S.C. 5704(e) provides that manufacturers of tobacco products may remove tobacco products for experimental purposes without payment of Federal excise tax, as prescribed by regulation. Under that authority, the TTB regulations at 27 CFR 40.232(e) require the keeping of certain records regarding the shipment, description, use, and disposition of tobacco products removed for experimental purposes outside of the factory. Although the keeping of such records is a usual and customary business practice for manufacturers of tobacco products, these records provide TTB information that it uses to identify the lawful experimental use and disposition of nontaxpaid tobacco products, and to detect and prevent their diversion into the market.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1.

OMB Control Number: 1513–0111.

Type of Review: Revision of a currently approved collection.

Title: COLAs Online Access Request.

Form: TTB F 5013.2.

Abstract: Respondents use this form to apply for access to TTB's COLAs Online system, which allows alcohol beverage industry members to electronically apply for a Certificate of Label Approval or for an exemption from label approval. TTB uses the provided information to identify the company on whose behalf the applicant claims to act, to verify the scope of the applicant's authority to act, and to evaluate the applicant's qualifications for access to the COLAs Online system before TTB issues that person a password allowing access to this TTB information system. This is necessary to protect the COLAs Online system from unauthorized users and other threats.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 900.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–20985 Filed 8–30–16; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 26, 2016.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before September 30, 2016 to be assured of consideration.

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FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Financial Crimes Enforcement Network (FinCEN)

OMB Control Number: 1506–0009.

Type of Review: Extension of a previously approved collection.

Title: Financial Record-keeping and Reporting and Report of Foreign Bank and Financial Accounts.

Abstract: The Bank Secrecy Act authorizes Treasury to require financial institutions and individuals to keep records and file reports that the Treasury determines have a high degree of usefulness in criminal, tax, or regulatory matters, or to protect against international terrorism. The information collected assists federal, state, and local law enforcement in the identification, investigation, and prosecution of individuals involved in a variety of financial crimes.

Affected Public: Businesses or other for-profits; Farms, Not-for-profit institutions.

Estimated Total Annual Burden Hours: 1,007,210.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–20970 Filed 8–30–16; 8:45 am]

BILLING CODE 4810–02–P

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Part II

Department of Homeland Security

8 CFR Parts 103, 212, and 274a
International Entrepreneur Rule; Proposed Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 103, 212, and 274a

[CIS No. 2572–15; DHS Docket No. USCIS–2015–0006]

RIN 1615–AC04

International Entrepreneur Rule

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Proposed rule.

SUMMARY: The Department of Homeland Security (DHS) proposes to amend its regulations implementing the Secretary of Homeland Security's discretionary parole authority to increase and enhance entrepreneurship, innovation, and job creation in the United States. The proposed rule would add new regulatory provisions guiding the use of parole on a case-by-case basis with respect to entrepreneurs of start-up entities whose entry into the United States would provide a significant public benefit through the substantial and demonstrated potential for rapid business growth and job creation. Such potential would be indicated by, among other things, the receipt of significant capital investment from U.S. investors with established records of successful investments, or obtaining significant awards or grants from certain Federal, State or local government entities. If granted, parole would provide a temporary initial stay of up to 2 years (which may be extended by up to an additional 3 years) to facilitate the applicant's ability to oversee and grow his or her start-up entity in the United States. A subsequent request for re-parole would be considered only when the entrepreneur and his or her start-up entity continues to provide a significant public benefit as evidenced by substantial increases in capital investment, revenue, or job creation. DHS believes that a regulatory process for seeking and granting parole in this business-creation context—including by establishing criteria for evaluating individual parole applications on a case-by-case basis—is important given the complexities involved in such adjudications and the need for guidance regarding the general criteria for eligibility by the start-up entrepreneurs, entities, and investors involved.

DATES: Written comments must be received on or before October 17, 2016.

ADDRESSES: You may submit comments, identified by DHS Docket No. USCIS–2015–0006, by any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *Email:* You may submit comments directly to U.S. Citizenship and Immigration Services (USCIS) by email at *uscisfrcomment@dhs.gov.* Please include DHS docket number USCIS–2015–0006 in the subject line of the message.
- *Mail:* You may submit comments directly to USCIS by mail by sending correspondence to Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529. To ensure proper handling, please reference DHS Docket No. USCIS–2015–0006 in your correspondence. This mailing address may be used for paper, disk, or CD–ROM submissions.
- *Hand Delivery/Courier:* You may submit comments directly to USCIS through hand delivery to: Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529; Telephone (202) 272–8377. To ensure proper handling, please reference DHS Docket No. USCIS–2015–0006 in your correspondence.

FOR FURTHER INFORMATION CONTACT: Steven Viger, Adjudications Officer, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Suite 1100, Washington, DC 20529–2140; Telephone (202) 272–8377.

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I. Public Participation

DHS invites comments, data, and information from all interested parties, including advocacy groups, nongovernmental organizations, community-based organizations, entrepreneurs, investors, other entities in the entrepreneurial ecosystem of the United States, and legal representatives who specialize in immigration law on any and all aspects of this proposed rule. Comments that will provide the most assistance to DHS in developing these procedures will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authorities that support such recommended change. DHS is generally seeking comments on:

A. Proposed filing requirements and procedures;

B. Proposed definitions and criteria for evaluating parole applications, including investment, award, revenue, job creation, and alternative criteria;

C. Proposed conditions, including limits on the number of entrepreneur parolees per start-up entity and time limits on parole periods;

D. Proposed provisions establishing employment authorization for entrepreneurs incident to parole;

E. Proposed provisions regarding termination of parole; and

F. Proposed opportunity to request re-parole, length of period for re-parole, and limitation on number of re-parole opportunities.

DHS also invites comments on the economic analysis supporting this rule and the proposed new parole request form for entrepreneurs.

Instructions: All submissions must include the agency name and the DHS Docket No. USCIS–2015–0006 for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

II. Executive Summary

A. Purpose of the Regulatory Action

Section 212(d)(5) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(5), grants the Secretary of Homeland Security the discretionary authority to parole individuals into the United States, on a case-by-case basis, for urgent humanitarian reasons or significant public benefit. DHS proposes to amend its regulations implementing this authority to increase and enhance entrepreneurship, innovation, and job creation in the United States. As described in more detail below, the proposed rule would establish general criteria for the use of parole with respect to entrepreneurs of start-up entities whose entry into the United States would provide a significant public benefit through the substantial and demonstrated potential for rapid growth and job creation. In all cases, whether to parole a particular individual under this rule would be a discretionary determination that would be made on a case-by-case basis.

Given the complexities involved in adjudicating applications in this context and the need for guidance regarding the criteria for exercising parole in this area, DHS has decided to establish by regulation the criteria for the case-by-case evaluation of parole applications filed by entrepreneurs of start-up entities. By including such criteria in regulation, as well as establishing application requirements that are specifically tailored to capture the necessary information for processing parole requests on this basis, DHS expects to facilitate the use of parole in this area.

As discussed, the proposed rule would establish criteria for seeking and obtaining parole based on the creation of a start-up entity in the United States. DHS proposes that to be considered for parole under this rule, an applicant would need to demonstrate that his or her parole would provide a significant public benefit because he or she is the entrepreneur of a new start-up entity in the United States that has significant potential for rapid growth and job creation. DHS proposes that such potential would be indicated by, among other things, the receipt of (1) significant capital financing from U.S. investors with established records of successful investments or (2) significant awards or grants from certain Federal, State or local government entities. DHS also proposes alternative criteria for applicants who partially meet the proposed thresholds for capital financing or government awards or grants and who can provide additional reliable and compelling evidence of their entities' significant potential for rapid growth and job creation. An applicant would qualify for further consideration by showing that he or she has a substantial ownership interest in such an entity, has an active and central role in the entity's operations, and would substantially further the entity's ability to engage in research and development or otherwise conduct and grow its business in the United States. The grant of parole is intended to facilitate the applicant's ability to oversee and grow the start-up entity.

DHS believes that this proposal would encourage foreign entrepreneurs to create and develop start-up entities with high growth potential in the United States, which are expected to facilitate research and development in the country, create jobs for U.S. workers, and otherwise benefit the U.S. economy through increased business activity, innovation and dynamism. Particularly in light of the complex considerations involved in entrepreneur-based parole requests, DHS also believes that this proposal will provide a transparent framework by which DHS will exercise its discretion to adjudicate such requests on a case-by-case basis under section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5).

B. Legal Authority

The Secretary of Homeland Security's authority for the proposed regulatory amendments can be found in various provisions of the immigration laws. Section 402(4) of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 202(4), provides the Secretary the authority to administer and enforce the immigration and nationality laws. Sections 103(a)(1) and (3) of the INA, 8 U.S.C. 1103(a)(1), (3), expressly authorize the Secretary to establish rules and regulations governing parole. Section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5), vests in the Secretary the discretionary authority to grant parole for urgent humanitarian reasons or significant public benefit to applicants for admission on a case-by-case basis.[1] Section 274A(h)(3)(B) of the INA, 8 U.S.C. 1324a(h)(3)(B), recognizes the Secretary's general authority to extend employment authorization to noncitizens in the United States. And section 101(b)(1)(F) of the HSA, 6 U.S.C. 111(b)(1)(F), establishes as a primary mission of DHS the duty to "ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland."

C. Summary of Proposed Amendments

DHS is proposing to add a new section 8 CFR 212.19 to provide guidance with respect to the use of parole for entrepreneurs of start-up entities based upon significant public benefit. An individual seeking to operate and grow his or her start-up entity in the United States would generally need to demonstrate the following to be considered for a discretionary grant of parole under this proposed rule:

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[1] In sections 402 and 451 of the HSA, Congress transferred from the Attorney General to the Secretary of Homeland Security the general authority to enforce and administer the immigration laws, including those pertaining to parole. In accordance with section 1517 of title XV of the HSA, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS "shall be deemed to refer to the Secretary" of Homeland Security. *See* 6 U.S.C. 557 (codifying the HSA, tit. XV, section 1517). Authorities and functions of DHS to administer and enforce the immigration laws are appropriately delegated to DHS employees and others in accordance with section 102(b)(1) of the HSA, 6 U.S.C. 112(b)(1); section 103(a) of the INA, 8 U.S.C. 1103(a); and 8 CFR 2.1.

1. *Formation of New Start-Up Entity.* The applicant has recently formed a new entity in the United States that has lawfully done business since its creation and has substantial potential for rapid growth and job creation. DHS proposes that an entity may be generally considered recently formed if it was created within the 3 years preceding the date of the filing of the initial parole application.

2. *Applicant is an Entrepreneur.* The applicant is an entrepreneur of the start-up entity who is well-positioned to advance the entity's business. DHS proposes that an applicant may generally meet this standard by providing evidence that he or she: (1) Possesses a significant (at least 15 percent) ownership interest in the entity at the time of adjudication of the initial grant of parole; and (2) has an active and central role in the operations and future growth of the entity, such that his or her knowledge, skills, or experience would substantially assist the entity in conducting and growing its business in the United States. Such an applicant cannot be a mere investor.

3. *Significant U.S. Capital Investment or Government Funding.* The applicant can further validate, through reliable supporting evidence, the entity's substantial potential for rapid growth and job creation. DHS proposes that an applicant may be able to satisfy this criterion in one of several ways:

a. *Investments from established U.S. investors.* The applicant may show that the entity has received significant investment of capital from certain qualified U.S. investors with established records of successful investments. DHS proposes that an applicant would generally be able to meet this standard by demonstrating that the start-up entity has received investments of capital totaling $345,000 or more from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities.

b. *Government grants.* The applicant may show that the start-up entity has received significant awards or grants from Federal, State or local government entities with expertise in economic development, research and development, and/or job creation. DHS proposes that an applicant would generally be able to meet this standard by demonstrating that the start-up entity has received monetary awards or grants totaling $100,000 or more from government entities that typically provide such funding to U.S. businesses for economic, research and development, or job creation purposes.

c. *Alternative criteria.* DHS further proposes alternative criteria under which an applicant who partially meets one or more of the above sub-criteria related to capital investment or government funding may be considered for parole under this rule if he or she provides additional reliable and compelling evidence that his or her entry would provide a significant public benefit to the United States. Such evidence would need to serve as a compelling validation of the entity's substantial potential for rapid growth and job creation.

DHS proposes that an applicant who meets the above criteria (and his or her spouse and minor, unmarried children, if any) generally may be considered under this rule for a discretionary grant of parole lasting up to 2 years based on the significant public benefit that would be provided by the applicant's (or family's) parole into the United States. An applicant would be required to file a new application specifically tailored for entrepreneurs to demonstrate eligibility for parole based upon significant public benefit under this rule, along with proposed fees. Applicants would also be required to appear for collection of biometric information. DHS further proposes that no more than three entrepreneurs may receive parole with respect to any one qualifying entity.

USCIS adjudicators would be required to consider the totality of the evidence, including evidence obtained by USCIS through background checks and other means, to determine whether the applicant has satisfied the above criteria, whether the specific applicant's parole would provide a significant public benefit, and whether negative factors exist that warrant denial of parole as a matter of discretion. To grant parole, adjudicators would be required to conclude, based on the totality of the circumstances, that both: (1) The applicant's parole would provide a significant public benefit, and (2) the applicant merits a grant of parole as a matter of discretion.

DHS further proposes that if parole is granted, the entrepreneur would be authorized for employment incident to the grant of parole, but only with respect to the entrepreneur's start-up entity. The entrepreneur's spouse and children, if any, would not be authorized for employment incident to the grant of parole, but the entrepreneur's spouse, if paroled into the United States pursuant to 8 CFR 212.19, would be permitted to apply for employment authorization consistent with proposed 8 CFR 274a.12(c)(34). DHS retains the right to revoke any such grant of parole at any time as a matter of discretion or if the Department determines that parole no longer provides a significant public benefit, such as when the entity has ceased operations in the United States or DHS believes that the application involves fraud or misrepresentation.

As noted, the purpose of the proposed parole process is to provide qualified entrepreneurs of high-potential start-up entities in the United States with the improved ability to conduct research and development and expand the entities' operations in the United States so that our nation's economy may benefit from such development and expansion, including through increased capital expenditures, innovation and job creation. DHS proposes to allow individuals granted parole under this rule to be considered for re-parole for an additional period of up to 3 years if, and only if, they can demonstrate that their entities have shown signs of significant growth since the initial grant of parole and such entities continue to have substantial potential for rapid growth and job creation. As proposed, an applicant under this rule would generally need to demonstrate the following to be considered for a discretionary grant of an additional period of parole:

1. *Continuation of Start-Up Entity.* The entity continues to be a start-up entity as defined by the proposed rule. For purposes of seeking re-parole, an applicant would be able to meet this standard by showing that the entity: (a) Has been lawfully operating in the United States during the period of parole; and (b) continues to have substantial potential for rapid growth and job creation.

2. *Applicant Continues to Be an Entrepreneur.* The applicant continues to be an entrepreneur of the start-up entity who is well-positioned to advance the entity's business. DHS proposes that an applicant may generally meet this standard by providing evidence that he or she: (a) Continues to possess a significant (at least 10 percent) ownership interest in the entity; and (b) continues to have an active and central role in the operations and future growth of the entity, such that his or her knowledge, skills, or experience would substantially assist the entity in conducting and continuing to grow its business in the United States. This reduced ownership amount takes into account the need of some successful start-up entities to raise additional venture capital financing by selling ownership interest during their initial years of operation.

3. *Significant U.S. Investment/Revenue/Job Creation.* The applicant can further validate, through reliable supporting evidence, the start-up entity's continued potential for rapid growth and job creation. DHS proposes that an applicant would be able to satisfy this criterion in one of several ways:

a. *Investments from established U.S. investors.* The applicant may show that during the initial period of parole the start-up entity received additional substantial investments of capital, including through qualified investments from U.S. investors with established records of successful investments; significant awards or grants from government entities that regularly provide such funding to start-up entities; or a combination of both. DHS proposes that an applicant would generally be expected to demonstrate that the entity received at least $500,000 in additional qualifying funding during the initial parole period. As noted previously, any private investments must be made by qualified U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial investment in successful start-up entities. Government awards or grants must be from Federal, State or local government entities with expertise in economic development, research and development, and/or job creation.

b. *Revenue generation*. The applicant may show that the start-up entity has generated substantial and rapidly increasing revenue in the United States during the initial parole period. DHS proposes that an applicant would generally be expected to demonstrate that the entity reached at least $500,000 in annual revenue, with average annualized revenue growth of at least 20 percent, during the initial parole period.

c. *Job creation*. The applicant may show that the start-up entity has demonstrated substantial job creation in the United States during the initial parole period. DHS proposes that an applicant would generally be expected to demonstrate that the entity created at least 10 full-time jobs for U.S. workers during the initial parole period.

d. *Alternative criteria*. As with initial parole, DHS further proposes alternative criteria under which an applicant who partially meets one or more of the above sub-criteria related to capital investment, revenue generation, or job creation may be considered for re-parole under this rule if he or she provides additional reliable and compelling evidence that his or her parole would continue to provide a significant public benefit. As discussed above, such evidence would need to serve as a compelling validation of the entity's substantial potential for rapid growth and job creation.

DHS proposes that an applicant who generally meets the above criteria may be considered for one additional grant of parole to work with the same start-up entity based on the significant public benefit that would be served by his or her continued parole in the United States, if the applicant also merits a favorable exercise of discretion. If granted, re-parole may be for up to 3 years, for a total maximum period of 5 years for parole under 8 CFR 212.19. No more than three entrepreneurs (and their spouses and children) may receive such additional periods of parole with respect to any one qualifying entity.

As with initial parole applications, USCIS adjudicators would be required to consider the totality of the evidence, including evidence obtained by USCIS through verification methods, to determine whether the applicant has satisfied the above criteria and whether his or her continued parole would provide a significant public benefit. To re-parole, adjudicators would be required to conclude, based on the totality of the circumstances, both: (1) That the applicant's continued parole would provide a significant public benefit, and (2) that the applicant continues to merit parole as a matter of discretion. If re-paroled, DHS retains the right to revoke parole at any time as a matter of discretion or if the Department determines that parole no longer provides a significant public benefit, such as when the entity has ceased operations in the United States or DHS believes that the applicant committed fraud or made material misrepresentations.

Finally, DHS is proposing conforming changes to the employment authorization regulations at 8 CFR 274a.12(b) and (c), the employment eligibility verification regulations at 8 CFR 274a.2(b), and fee regulations at 8 CFR 103.7(b)(i). The proposed rule would amend 8 CFR 274a.12(b) by: (1) Adding entrepreneur parolees to the classes of aliens authorized for employment incident to their immigration status or parole, and (2) providing for temporary employment authorization for those applying for re-parole. The proposed rule would amend 8 CFR 274a.12(c) by extending eligibility for employment authorization to the spouse of an entrepreneur paroled into the United States under 8 CFR 212.19. The proposed rule would amend 8 CFR 274a.2(b) by designating the entrepreneur's foreign passport and Arrival/Departure Record (Form I–94) indicating entrepreneur parole as acceptable evidence for employment eligibility verification (Form I–9) purposes.[2] Finally, the proposed rule would amend 8 CFR 103.7(b)(i) by including the fee for the new proposed application form.

D. Costs and Benefits

DHS does not anticipate that this rule, if finalized, would generate significant costs and burdens to private or public entities. Costs of the rule would stem from filing fees and opportunity costs associated with applying for parole, and the requirement that the entrepreneur alert DHS to any material changes.

DHS estimates that 2,940 entrepreneurs could be eligible for parole annually. Each applicant for parole would face a total filing cost—including the application form fee, biometric filing fee, travel costs, and associated opportunity costs—of $1,480, resulting in a total cost of $4,349,827 (undiscounted) for the first full year the rule could take effect and any subsequent year. Additionally, dependent family members (spouses and children) seeking parole with the principal applicant would be required to file an Application for Travel Document (Form I–131) and submit biographical information and biometrics. DHS estimates approximately 3,234 dependent spouses and children could seek parole based on the base estimate of 2,940 principal applicants. Each spouse and child 14 years of age and older seeking parole would face a total cost of $550 per applicant, for a total aggregate cost of $1,779,604.[3] Additionally, spouses who apply for work authorization via a Form I–765 application would incur a total additional cost of $416.20 each. Based on the same number of entrepreneurs, the estimated 2,940 spouses[4] would incur total costs of $1,223,630 (undiscounted). The total cost of the rule to include direct filing costs and monetized non-filing costs is estimated to be $7,353,061 annually.

DHS anticipates that establishing a parole process for those entrepreneurs who stand to provide a significant public benefit would advance the U.S. economy by enhancing innovation, generating capital investments, and creating jobs. DHS does not expect significant negative consequences or labor market impacts from this rule; indeed, DHS believes this proposal would encourage entrepreneurs to pursue business opportunities in the United States rather than abroad, which can be expected to generate significant scientific, research and development, and technological impacts that could create new products and produce positive spillover effects to other businesses and sectors. The impacts stand to benefit the economy by supporting and strengthening high-growth, job-creating businesses in the United States.

III. Background

A. Discretionary Parole Authority

The Secretary of Homeland Security has discretionary authority to grant temporary parole "under conditions as he may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit [to] any individual applying for admission to the United States." INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).[5] The Secretary's parole authority is expansive. Congress did not define the phrase "urgent humanitarian reasons or significant public benefit," entrusting interpretation and application of those standards to the Secretary. Aside from requiring case-by-case determinations, Congress limited the parole authority by prohibiting its use with respect to two classes of applicants for admissions: (1) Aliens who are refugees (unless the Secretary determines that parole is required for a particular alien for compelling reasons in the public interest), *see* INA section 212(d)(5)(B), 8 U.S.C. 1182(d)(5)(B); and (2) alien crewmen during certain labor disputes, *see* INA section 214(f)(2)(A), 8 U.S.C. 1184(f)(2)(A).

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[2] Additionally, DHS is also proposing a technical change to this section to add the Department of State (DOS) Consular Report of Birth Abroad (Form FS–240, or successor form) to the "List C" column of acceptable documents for Form I–9 purposes.

[3] For parole requests for children under the age of 14, only the filing fee will be required, as they do not appear for biometric collection. Applicants under the age of 14 and over the age of 79 are not required to be fingerprinted. However, they may still be required to attend a biometrics appointment in order to have their photograph and signature captured.

[4] DHS used a simple one-to-one mapping of entrepreneurs to spouses to obtain 1,813 spouses, the same number as entrepreneur parolees.

Parole decisions are discretionary determinations and must be made on a case-by-case basis consistent with the INA. DHS may exercise its authority to determine that an individual's parole into the United States is justified by urgent humanitarian reasons or significant public benefit. Even when one of those standards would be met, DHS may nevertheless deny parole as a matter of discretion based on other factors.[6] In making such discretionary determinations, USCIS considers all relevant information, including any criminal history or other serious adverse factors that would weigh against a favorable exercise of discretion.

Parole is not an admission to the United States. *See* INA section 101(a)(13)(B), 8 U.S.C. 1101(a)(13)(B); 8 CFR 1.2 ("An arriving alien remains an arriving alien even if paroled pursuant to section 212(d)(5) of the Act, and even after any such parole is terminated or revoked."). Parole may also be terminated at any time in DHS's discretion, consistent with existing regulations; in those cases, the individual is "restored to the status that he or she had at the time of parole." 8 CFR 212.5(e); *see also* INA section 212(d)(5), 8 U.S.C. 1182(d)(5).

DHS regulations at 8 CFR 212.5 describe DHS's discretionary parole authority for arriving aliens to the United States (other than detained aliens), including the authority to set the terms and conditions of parole. Some conditions are described in the regulations, including requiring reasonable assurances that the parolee will appear at all hearings and will depart from the United States when required to do so. *See* 8 CFR 212.5(d).

Each of the DHS immigration components—USCIS, U.S. Customs and Border Protection (CBP), and U.S. Immigration and Customs Enforcement (ICE)—has been delegated the authority to parole applicants for admission in accordance with section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5). *See* 8 CFR 212.5(a). The parole authority is often utilized to permit an alien who is outside the United States to travel to and come into the United States without a visa. USCIS, however, also accepts requests for "advance parole" by aliens who seek authorization to depart the United States and return to the country pursuant to parole in the future.[7] *See* 8 CFR 212.5(f); Application for Travel Document (Form I–131). Advance authorization of parole by USCIS does not guarantee that the alien will be paroled by CBP upon his or her appearance at a port of entry. Rather, with a grant of advance parole, the alien is issued a document authorizing travel (in lieu of a visa) indicating the presumption that CBP will favorably exercise discretion to parole the alien in the future (so long as material circumstances do not change).

Currently, upon an alien's arrival to the United States with a parole travel document (*e.g.*, a Department of State (DOS) foil, Authorization for Parole of an Alien into the United States (Form I–512L), or an Employment Authorization Document (Form I–766)), a CBP officer at a port of entry inspects the prospective parolee. If parole is authorized, the CBP officer issues an Arrival/Departure Record (Form I–94) documenting the grant of parole and the length of the parolee's authorized parole period. *See* 8 CFR 235.1(h)(2). Importantly, CBP retains the authority to deny parole to a parole applicant or to modify the length of advance parole authorized by USCIS. *See* 8 CFR 212.5(c).

Because parole does not constitute an admission, individuals may be paroled into the United States even if they are inadmissible. *See* section 212(a) of the INA, 8 U.S.C. 1182(a). Further, parole does not confer any immigration "status." *See* section 101(a)(13)(B) of the INA, 8 U.S.C. 1101(a)(13)(B); section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A). Parole does not provide a parolee with temporary nonimmigrant status or lawful permanent resident status. Nor does it provide the parolee with a basis for changing status to that of a nonimmigrant or adjusting status to that of a lawful permanent resident, unless the parolee is otherwise eligible.

Under current regulations, once paroled into the United States, a parolee is eligible to request employment authorization from USCIS by filing an Application for Employment Authorization (Form I–765) with USCIS. *See* 8 CFR 274a.12(c)(11). If employment authorization is granted, USCIS issues the parolee an EAD with an expiration date that is commensurate with the period of parole on the parolee's Arrival/Departure Record (Form I–94). The parolee may use this EAD to demonstrate identity and employment authorization to an employer for Form I–9 verification purposes as required by section 274A(a) and (b) of the INA, 8 U.S.C. 1324a(a) and (b). Under current regulations, the parolee is not employment authorized by virtue of being paroled, but instead only after receiving a discretionary grant of employment authorization from USCIS based on the Application for Employment Authorization.

Parole may terminate automatically upon the expiration of the authorized parole period or upon the departure of the individual from the United States. *See* 8 CFR 212.5(e)(1). Parole also may be terminated on written notice when DHS determines that the individual no longer warrants parole or through the service of a Notice to Appear (NTA). *See* 8 CFR 212.5(e)(2)(i).

B. Historical Uses of Parole

DHS and the former Immigration and Naturalization Service (INS) have long extended parole to individuals for urgent humanitarian reasons or significant public benefit. The authority has been exercised on behalf of individuals on an ad hoc basis, as well as through policy guidance or regulations identifying classes of individuals to be considered for parole through individualized case-by-case adjudications. For example, parole has long been used on an ad hoc basis for individuals with serious medical conditions who need to come into the United States for medical treatment, individuals subject to prosecution or who are required to testify in court, individuals cooperating with law enforcement agencies, volunteers offering assistance in response to natural or other disasters, and foreign officials and other dignitaries who are inadmissible but seek to attend events in the country. Depending on the circumstances, such uses of parole have been justified on "urgent humanitarian" or "significant public benefit" grounds, or both.

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[5] Although section 212(d)(5) continues to refer to the Attorney General, the parole authority now resides exclusively with the Secretary of Homeland Security. *See Matter of Arrabally*, 25 I. & N. Dec. 771, 777 n.5 (BIA 2012).

[6] The denial of parole is not subject to judicial review. *See* INA section 242(a)(2)(B)(ii), 8 U.S.C. 1252(a)(2)(B)(ii).

[7] Aliens who seek parole as entrepreneurs under this rule may need to apply for advance parole if at the time of application they are present in the United States after admission in a nonimmigrant classification, as USCIS is unable to grant parole to aliens who are not "applicants for admission." *See* INA section 212(d)(5), 8 U.S.C. 1182(d)(5).

Parole has also long been exercised on a case-by-case basis with respect to individuals falling within certain designated parameters, as defined through regulation or policy guidance. Longstanding regulations, for example, provide discretionary criteria and other guidance for the use of parole with respect to arriving aliens detained in the United States. *See* 8 CFR 212.5. Those regulations provide that parole from immigration custody generally would be "justified" on a case-by-case basis if an individual falls within one of several specific categories, including individuals with serious medical conditions, pregnant women, juveniles, or individuals whose "continued detention is not in the public interest" as determined by certain listed officials. *Id.* Through longstanding policy memoranda or other guidance, DHS and the former INS have also provided instructions on the use of parole for other individuals, including certain vulnerable individuals who have been denied refugee status.

More recently, DHS has provided guidance on the case-by-case exercise of the parole authority through policy memoranda or notices in the **Federal Register**, including, for example, on behalf of certain Cuban nationals, certain individuals seeking to enter the Commonwealth of the Northern Mariana Islands (CNMI), and certain family members of U.S. military personnel:

- In 2007, DHS implemented the Cuban Family Reunification Parole Program to promote safe, legal, and orderly migration as an alternative to maritime crossings from Cuba. This program offers Cuban beneficiaries of approved family-based immigrant visa petitions an opportunity to apply for parole rather than remain in Cuba while awaiting the availability of an immigrant visa number.[8] USCIS implemented the program based on the significant public benefit rationales of "enabling the United States to meet its commitments under the Migration Accords" and "reducing the perceived need for family members left behind in Cuba to make irregular and inherently dangerous attempts to arrive in the United States." [9]
- In 2009, DHS announced a policy on the use of parole into the CNMI for certain foreign workers, as well as visitors from the Russian Federation and the People's Republic of China.[10] The parole policy was justified based on the economic benefit such workers and visitors would provide to the U.S. territory.
- In 2013, DHS issued guidance encouraging the use of parole for spouses, children, and parents of active duty members of the U.S. Armed Forces, individuals in the Selected Reserve of the Ready Reserve, and individuals who previously served in the U.S. Armed Forces or the Selected Reserve of the Ready Reserve.[11] The cited benefits included mitigating the adverse effects on Service Members and military preparedness stemming from the stress and anxiety of their immediate family members due to immigration concerns.

C. Significant Public Benefit From Attracting Foreign Entrepreneurs to the United States

DHS believes that enabling foreign entrepreneurs to establish and grow their start-up entities in the United States, rather than abroad, would yield a significant public benefit in certain cases. This would be expected to promote entrepreneurship and investment; facilitate research and development and other forms of innovation; support the continued growth of the U.S. economy; and lead to job creation for U.S. workers. To this end, DHS has considered the economic benefits of foreign entrepreneurs.

Evidence indicates that young business ventures, especially new start-up businesses, are important economic drivers and that the U.S. economy significantly benefits from the economic activity generated by entrepreneurs who start and grow new businesses here rather than abroad.[12] Indeed, evidence suggests that future economic and job growth for nations will hinge heavily on their ability to attract entrepreneurs, including those from abroad.[13] As entrepreneurs have increasing opportunities to establish and operate their start-up entities around the world, the need to create conditions that reduce barriers to entry and attract entrepreneurs has become a priority policy goal for a number of economically advanced and less economically advanced nations.[14] To compete for talented entrepreneurs, these countries have, or are planning to have, processes similar to that proposed in this rule.[15]

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[8] Cuban Family Reunification Parole Program, 72 FR 65,588 (Nov. 21, 2007); see also Changes to Application Procedures for the Cuban Family Reunification Parole Program, 79 FR 75579 (Dec. 18, 2014).

[9] *Id.*

[10] *See* 8 CFR 214.2(w)(1)(v); USCIS, Commonwealth of the Northern Mariana Islands (CNMI) Federalization of Immigration Law (Sept. 22, 2014), *available at http://www.uscis.gov/laws/immigration-commonwealth-northern-mariana-islands-cnmi/commonwealth-northern-mariana-islands-cnmi-federalization-immigration-law;* USCIS, Extending Parole in the CNMI (Jan. 30, 2012), *available at http://www.uscis.gov/laws/immigration-commonwealth-northern-mariana-islands-cnmi/extending-parole-cnmi.*

[11] *See* USCIS Policy Mem. PM–602–0091, Parole of Spouses, Children and Parents of Active Duty Members of the U. S. Armed Forces, the Selected Reserve of the Ready Reserve, and Former Members of the U.S. Armed Forces or Selected Reserve of the Ready Reserve and the Effect of Parole on Inadmissibility under Immigration and Nationality Act § 212(a)(6)(A)(i) at 2–3 (Nov. 13, 2013), *available at http://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/2013/2013-1115_Parole_in_Place_Memo_.pdf.*

[12] *See, e.g.* Edward L. Glaeser, Sari Pekkala Kerr, and William R. Kerr "Entrepreneurship And Urban Growth: An Empirical Assessment With Historical Mines" (2013). Working Papers 13–15, Center for Economic Studies, U.S. Census Bureau. (Finding that increasing the proportion of startup employment within a region increases the growth rate of overall employment and wages.); John C. Haltiwanger, Ron S. Jarmin, Javier Miranda, "Who Creates Jobs? Small vs. Large vs. Young" NBER Working Paper No. 16300, August 2010, available at *http://www.nber.org/papers/w16300* (Findings "highlight the important role of business startups and young businesses in U.S. job creation."); Jose Plehn-Dujowich, "Product Innovations by Young and Small Firms," Small Business Administration, Research Summary No. 408 available at *http://www.sba.gov/advocacy/7540/621871* (Finding that "innovation is characteristic of both young and small firms"); Tim Kane, "The Importance of Startups in Job Creation and Job Destruction," July 2010 Kauffman Foundation Research Series: Firm Formation and Economic Growth, available at *http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2010/07/firm_formation_importance_of_startups.pdf* (showing the importance of startups for net job growth in the U.S. economy).

[13] Council of Economic Advisers The Economic Effects of Administrative Action on Immigration, 18 (November 2014, updated February 2015), available at *https://www.whitehouse.gov/sites/defaulUfiles/docs/economic_effects_of_immigration_ea_february_2015_update_final_v2.pdf* ("A body of academic research conducted over the past ten years has found that high-skilled immigration has positive effects on innovation (as measured by patenting) and on total factor productivity."); Robert Litan, *Start-Up Slowdown;* Council on Foreign Relation, Jan./Feb. 2015, available at *https://www.foreignaffairs.com/articles/americas/2014-12-15/start-slowdown;* Robert Fairlie, *Kauffman Index of Entrepreneurial Activity, 1996–2011,* Ewing Marion Kauffman Foundation, March 19, 2012, *http://www.kauffman.org/uploadedfiles/kiea_2012_report.pdf* (finding that immigrants were more than twice as likely as Americans to start new businesses in 2011); Madeleine Sumption, "Visas for Entrepreneurs: How Countries Are Seeking Out Immigrant Job Creators," June 13, 2012 Migration Information Source, Migration Institute, available at *http://www.migrationpolicy.org/article/visas-entrepreneurs-how-countries-are-seeking-out-immigrant-job-creators.*

[14] Robert Litan, "Start-Up Slowdown"; Council on Foreign Relation, Jan./Feb. 2015, available at *https://www.foreignaffairs.com/articles/americas/2014-12-15/start-slowdown;* Madeleine Sumption, "Visas for Entrepreneurs: How Countries Are Seeking Out Immigrant Job Creators," June 13, 2012 Migration Information Source, Migration Institute, available at *http://www.migrationpolicy.org/article/visas-entrepreneurs-how-countries-are-seeking-out-immigrant-job-creators.*

[15] Canada Start-up Visa, *http://www.cic.gc.ca/english/immigrate/business/start-up/;* UK Tier 1 (Entrepreneur) visa, *https://www.gov.uk/tier-1-entrepreneur/overview.*

Allowing certain qualified entrepreneurs to come to the United States as parolees on a case-by-case basis would produce a significant public benefit through substantial and positive contributions to innovation, economic growth, and job creation. New business ventures, especially start-up businesses, are important economic drivers.[16] A significant percentage of the employment generated by high-tech manufacturers backed by U.S. venture capital investment has come from immigrant-founded companies.[17] A study on the top 50 venture capital-funded start-up companies in the United States showed that 48 percent had at least one immigrant founder.[18]

Innovative foreign-born entrepreneurs are critical forces in the U.S. economy, having founded roughly one-quarter of technology and engineering companies created between 2006 and 2012.[19] As of June 2013, publicly-traded immigrant-founded venture-backed companies had a total market capitalization of $900 billion.[20] Another study by the National Venture Capital Association found that 40 percent of the immigrant founders in the survey entered the United States as employment-sponsored immigrants, 38 percent as international students, 13 percent as family-sponsored immigrants, and the rest in other categories.[21] These studies, however, do not reflect the number of entrepreneurs who may have decided to start businesses in other countries because of the difficulty in locating their businesses in the United States due to current immigration policies.[22] The full potential of foreign entrepreneurs to benefit the U.S. economy through, for example, cutting-edge research, revenue generation, and job creation, is thus unknown. That current immigration policies create barriers for foreign entrepreneurs was a primary conclusion of the USCIS Entrepreneurs in Residence (EIR) program,[23] which was launched in 2012 to better understand how entrepreneurs fit within existing immigration classifications and to make policy recommendations based on its findings.

D. Proposal for Parole for Entrepreneurs

DHS proposes to exercise its parole authority, on a case-by-case basis, for entrepreneurs of start-up entities whose parole into the United States would provide a significant public benefit through the substantial potential of his or her start-up entity for rapid growth and job creation. Under the proposed rule, such potential would be evidenced by, among other things, the receipt of (1) substantial significant capital financing by U.S. investors with established records of successful investments or (2) significant awards or grants from certain government entities. DHS also proposes alternative criteria for applicants who partially meet the proposed thresholds for capital financing or government awards or grants and who can provide additional reliable and compelling evidence of their entities' significant potential for rapid growth and job creation.

If granted, parole would be authorized for up to 2 years to facilitate the entrepreneur's ability to oversee and grow his or her start-up entity in the United States. A subsequent request for re-parole would be considered only if the start-up entity continues to show significant promise of rapid growth and job creation through substantial and demonstrated increases in qualifying funding (whether capital investment or government grants or awards), revenue, or job creation. In all cases, whether to parole a particular individual under this rule would be a discretionary determination that would be made on a case-by-case basis. DHS believes that a regulatory process for seeking and granting parole in this business-creation context—including by establishing criteria for evaluating individual parole applications on a case-by-case basis—is important given the complexities involved in such adjudications and the need for general guidance regarding the relevant factors for eligibility by the start-up entrepreneurs, entities, and investors involved.

IV. Proposed Changes

In this rule, DHS is proposing to add a new section 8 CFR 212.19 to its regulations to set forth application procedures and criteria specifically for considering parole requests filed by entrepreneurs of start-up entities. *See* proposed 8 CFR 212.19. Consistent with this new section, the proposed rule would also: (1) Amend 8 CFR 274a.12(b) to authorize entrepreneur parolees to work for their approved start-up entities in the United States, *see* proposed 8 CFR 274a.12(b)(37); (2) amend 8 CFR 274a.12(c) to extend eligibility for employment authorization to the spouses of entrepreneur parolees, *see* proposed 8 CFR 274a.12(c)(34); (3) make a conforming amendment to the employment eligibility verification regulations at 8 CFR 274a.2(b)(v)(A)(5) to allow entrepreneur parolees to use their foreign passports and Arrival/Departure Records (Forms I–94) indicating they have entrepreneur parole as evidence of identity and employment authorization for purposes of meeting the Employment Eligibility Verification (Form I–9) requirements, *see* proposed 8 CFR 274a.2(b)(v)(A)(5); and (4) amend 8 CFR 103.7(b)(1)(i) to include a fee for the new proposed entrepreneur parole application form, *see* proposed 8 CFR 103.7(b)(1)(i)(FFF).

A. Overview of Parole for Entrepreneurs

At the proposed section 8 CFR 212.19, DHS sets forth the application requirements and proposed criteria for extending discretionary parole, on a case-by-case basis, to entrepreneurs of start-up entities and their spouses and children. As required by statute, the entrepreneur must demonstrate that his or her parole into the United States would provide a significant public benefit. DHS proposes that an individual may meet that standard under this rule by demonstrating that his or her start-up entity has substantial potential for rapid growth and job creation and that his or her parole would significantly help the entity conduct and grow its business here. *See* proposed new 8 CFR 212.19(b)(2). As described in more detail below, an applicant would generally be able to meet this standard by demonstrating the following:

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[16] Tim Kane, "The Importance of Startups in Job Creation and Job Destruction," July 2010 Kauffman Foundation Research Series: Firm Formation and Economic Growth, available at *http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2010/07/firm_formation_importance_of_startups.pdf* (showing the importance of startups for net job growth in the U.S. economy); Edward L. Glaeser, Sari Pekkala Kerr, and William R. Kerr, "Entrepreneurship And Urban Growth: An Empirical Assessment With Historical Mines," Working Papers 13–15, Center for Economic Studies, U.S. Census Bureau, 2013 (finding that increasing the proportion of startup employment within a region increases the growth rate of overall employment and wages.); John C. Haltiwanger, Ron S. Jarmin, Javier Miranda, "Who Creates Jobs? Small vs. Large vs: Young," NBER Working Paper No. 16300, August 2010, available at *http://www.nber.org/papers/w16300* (highlighting "the important role of business startups and young businesses in U.S. job creation").

[17] Stuart Anderson & Michaela Platzer, "American Made: The Impact of Immigrant Entrepreneurs and Professionals on U.S. Competitiveness," National Venture Capital Association, Nov. 2006, at 11.

[18] Stuart Anderson, "Immigration Founders and Key Personnel in America's 50 Top Venture-Funded Companies," Dec. 2010, *available at http://www.nfap.com/pdf/NFAPPolicyBriefImmigrantFoundersandKeyPersonnelinAmericasTopVentureFundedCompanies.pdf.*

[19] Vivek Wadhwa, AnnaLee Saxenian & F. Daniel Siciliano, "America's New Immigrant Entrepreneurs: Then and Now," Kauffman Foundation, Oct. 2012, at 3, *available at http://www.kauffman.org/what-we-do/research/immigration-and-the-american-economy/americas-new-immigrant-entrepreneurs-then-and-now.*

[20] Stuart Anderson, "American Made 2.0: How Immigrant Entrepreneurs Continue to Contribute to the U.S. Economy," National Venture Capital Association, 2013, at 5, *available at http://nvca.org/research/stats-studies/.*

[21] Stuart Anderson, "American Made 2.0—How Immigrant Entrepreneurs Continue to Contribute to the U.S. Economy," supra 28.

[22] *See, e.g.,* Vivek Wadhwa, "The Immigrant Exodus" (Philadelphia: Wharton Digital Press) (2012); Amy Grenier, "Majority of U.S. Patents Granted to Foreign Individuals, Immigration Impact," April 11, 2014, available at *http://immigrationimpact.com/2014/04/11/majority-of-u-s-patents-granted-to-foreign-individuals/* (noting difficulties that foreign inventors face in coming to and staying in the United States).

[23] *See http://www.uscis.gov/about-us/entrepreneurs-residence-initiative/entrepreneurs-residence-eir.* For the EIR program, USCIS recruited both start-up experts from the private sector, using DHS's Loaned Executive Program, and internal immigration experts from across the agency. Working within the framework of current immigration law, the team set out with the overarching goal of optimizing existing visa categories used by entrepreneurs to provide pathways that are clear, consistent, and aligned with business realities.

- The entrepreneur's entity was recently formed (*i.e.*, generally within the 3 years immediately preceding the filing date of the entrepreneur's application for parole) in the United States and has the substantial potential for rapid growth and job creation. *See* proposed 8 CFR 212.19(a)(2).
- The applicant is an entrepreneur in that he or she possesses a substantial ownership interest (*i.e.*, generally 15 percent or more) in the entity and has an active and central role in the entity such that he or she is well-positioned to advance the entity's business. *See* proposed 8 CFR 212.19(a)(1).
- The entity has: (1) Received substantial investment from U.S. investors with established records of successful investments; or (2) received substantial awards or grants from certain Federal, State, or local government entities. *See* proposed 8 CFR 212.19(b)(2)(ii). Alternatively, an applicant who partially meets one or more of these two sub-criteria may be considered for parole if he or she provides additional reliable and compelling evidence that his or her parole would provide a significant public benefit. *See* proposed 8 CFR 212.19(b)(2)(iii).

Under the proposed rule, an applicant would file a new application specifically tailored for entrepreneurs to demonstrate eligibility for parole based upon significant public benefit, along with proposed fees. *See* proposed 8 CFR 212.19(b)(1). Applicants would also be required to appear for collection of biometric information. *See* proposed 8 CFR 212.19(e). To grant parole, USCIS adjudicators would be required to conclude, following an individualized assessment and based on the totality of the circumstances, that both: (1) The applicant's parole would provide a significant public benefit, and (2) the applicant merits a grant of parole as a matter of discretion. *See* proposed 8 CFR 212.19(d)(1).

If a determination is made that parole of the applicant would provide a significant public benefit, DHS may parole the entrepreneur for a period of up to 2 years, with an opportunity to apply for one additional period of parole of up to 3 years upon showing that parole would continue to provide a significant public benefit. *See* proposed 8 CFR 212.19(d)(2) and (h). DHS further proposes that no more than three principal entrepreneurs may receive parole with respect to any one qualifying entity. *See* proposed 8 CFR 212.19(f).

Following is a detailed discussion of the specific provisions proposed by DHS in this rulemaking.

B. Criteria for Initial Parole Consideration

To be considered for an initial grant of parole based on significant public benefit under this rule, DHS is proposing that the individual generally meet the following criteria:

1. Recent Formation of a Start-Up Entity

The key criterion under this proposed rule is the formation of a new entity in the United States that has substantial potential to rapidly increase revenue and create jobs for U.S. workers. DHS thus proposes that an applicant for parole under this rule be able to show that his or her start-up entity was recently formed in the United States, has lawfully done business during any period of operation since its date of formation, and has the substantial potential to experience rapid growth and job creation, including through the significant attraction of capital investment or government awards or grants. *See* proposed 8 CFR 212.19(a)(2). An entity that is the basis for a request for parole under this section may be considered "recently formed" if it is a U.S. business entity that was created within the 3 years immediately preceding the filing date of the entrepreneur's application for parole. *Id.*

As a preliminary matter, DHS proposes that a proffered start-up entity must meet the definition of "U.S. business entity" at proposed 8 CFR 212.19(a)(9). The term is defined as any corporation, limited liability company, partnership, or other entity that is organized under Federal law or the laws of any State,[24] and that conducts business in the United States that is not an investment vehicle primarily engaged in the offer, purchase, sale or trading of securities, futures contracts, derivatives or similar instruments. *See* proposed 8 CFR 212.19(a)(9). DHS believes that this definition appropriately captures the range of start-up entities that are formed in the United States by entrepreneurs and that have the substantial potential for rapid growth and job creation. DHS is proposing to exclude an entity that is an investment vehicle primarily engaged in the offer, purchase, sale or trading of securities, futures contracts, derivatives or similar instruments to ensure that the start-up entities receiving investment capital under this proposed rule are not merely serving as a conduit for reinvestment, but providing or seeking to provide goods or services with the substantial potential for rapid growth and job creation.

As noted above, an entity must be recently formed in the United States to be considered a start-up entity for purposes of this rule. *See* proposed 8 CFR 212.19(a)(2). DHS proposes that an entity that is the basis for seeking parole under this rule may be considered recently formed if it is less than 3 years old at the time of filing the parole application.[25] *Id.* This limitation reflects the Department's intention for parole under this proposed rule to incentivize and support the creation and growth of new businesses in the United States, so that the country may benefit from their potential for rapid growth and job creation. DHS recognizes that the term "start-up" is usually used to refer to entities in early stages of development, including various financing rounds used to raise capital and expand the new business, but "goes beyond a company just getting off the ground." [26] DHS believes that limiting the definition of "start-up" in this proposed rule to entities that are less than 3 years old at the time the parole application is filed is reasonable to ensure that the entrepreneur's entity is the type of new business likely to experience rapid growth and job creation, while still allowing a reasonable amount of time for the entrepreneur to form the business, obtain qualifying levels of investor financing (which may occur in several rounds) or government grants or awards, and still meet the definition of a "start-up entity" under this rule.

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[24] "State" is a defined term at INA section 101(a)(36). In addition to the 50 States, the term "includes the District of Columbia, Puerto Rico, Guam, the Virgin Islands of the United States, and the Commonwealth of the Northern Mariana Islands."

[25] With respect to certain proposed definitions at 8 CFR 212.19(a)(3) and (a)(5), which discuss other entities that receive grants, awards, or investments, an entity may be considered recently formed if it was created within the 3 years immediately preceding the receipt of a relevant grant, award, or investment. *See* proposed 8 CFR 212.19(a)(2).

[26] U.S. Small Business Administration, Startups & High Growth Businesses, available at *https://www.sba.gov/content/startups-high-growth-businesses* ("In the world of business, the word 'startup' goes beyond a company just getting off the ground.").

DHS further proposes to consider parole under this rule only where it is demonstrated that the start-up entity has been operating lawfully in the United States since its formation. *See* proposed 8 CFR 212.19(a)(2). This limitation is intended to protect the integrity of this new parole process. Part of the parole determination would therefore include a review by DHS of the start-up entity's activities from the time of its formation in the United States.

Finally, DHS proposes that the start-up entity must be of a type that has the substantial potential to experience rapid growth and job creation, including through the significant attraction of capital investment or government awards or grants. This factor is intended to capture the types of start-up entities that are most likely to provide a significant public benefit, while excluding entities without such potential—such as small businesses with limited growth potential created by entrepreneurs for the sole or primary purpose of providing income to the entrepreneurs and their families.[27] Because this latter type of business is less likely to experience rapid growth and job creation, DHS believes it is unlikely that the entrepreneur of such a business would be able to meet the significant public benefit requirement for a grant of parole.

DHS anticipates that an applicant seeking parole under this rule would be able to meet the above criteria by providing various types of evidence. As part of the application process, an applicant would generally be expected to submit supporting documentation concerning the entity's business and its substantial potential for rapid growth and job creation (as well as the entrepreneur's day-to-day role in the business). *See* proposed 8 CFR 212.19(b)(2)(ii)(A). In addition to meeting the capital investment or government funding criteria discussed further below, such additional documentation may include:

- Evidence of capital investments from qualified investors, or government awards or grants, other than those relied on to satisfy the requirements of 8 CFR 212.19(b)(2)(ii)(B);
- letters from relevant government entities, qualified investors, or established business associations with knowledge of the entity's research, products or services and/or the applicant's knowledge, skills or experience that would advance the entity's business;
- newspaper articles or other similar evidence that the applicant or entity has received significant attention or recognition;
- evidence that the applicant or entity has been recently invited to participate in, is currently participating in, or has graduated from one or more established and reputable start-up accelerators;
- evidence of significant revenue generation and growth in revenue;
- patent awards or other documents indicating that the entity or applicant is focused on developing new technologies or cutting-edge research;
- evidence that the applicant has played an active and central role in the success of prior start-up entities;
- degrees or other documentation indicating that the applicant has knowledge, skills, or experience that would significantly advance the entity's business;
- payroll, bookkeeping, salary, or bank records or other documents related to jobs created prior to filing the request for parole; and
- any other relevant, probative, and credible evidence indicating the entity's potential for growth and/or the applicant's ability to advance the entity's business in the United States.

DHS believes that such evidence would assist USCIS officers in determining whether an entity has substantial potential for rapid growth and job creation and, ultimately, whether an applicant has met the required standard for parole and merits a favorable exercise of discretion.

DHS welcomes public comment on the proposed definitions of the terms "start-up entity" and "U.S. business entity," as well as the requirement that the entity be formed within the 3 years preceding a request for parole. DHS also welcomes comments on the types of evidence that may be considered when determining whether such provisions have been met, including alternative suggestions on how applicants may be able to demonstrate eligibility.

2. Applicant Is an Entrepreneur Who Is Well-Positioned To Advance the Entity's Business

DHS is proposing that to be considered for parole under this rule, an applicant must be an entrepreneur who is well-positioned to advance his or her start-up entity's business. Specifically, DHS proposes that an applicant be able to demonstrate that he or she is an "entrepreneur" as defined at 8 CFR 212.19(a)(1). This definition would require the applicant to show that he or she both: (1) Possesses a substantial ownership interest in the start-up entity, and (2) has a central and active role in the operations of that entity, such that his or her knowledge, skills, or experience will substantially assist the entity with the growth and success of its business. *See* proposed 8 CFR 212.19(a)(1). The definition further provides that for purposes of this rule, an individual may be considered to possess a substantial ownership interest if he or she possesses at least a 15 percent ownership stake in the start-up entity at the time of adjudication of the initial grant of parole (and maintains at least a 10 percent ownership stake in the start-up entity at all times during the parole period, including any period of re-parole). *Id.*

DHS believes these criteria are appropriate, as active ownership and participation provide stronger justifications for parole based on significant public benefit than investment alone. To establish that parole would serve a significant public benefit, DHS believes that the applicant should be central to the entity's business and well-positioned to actively assist in the growth of that business, such that his or her presence would help the entity provide related benefits in the United States, including by conducting research and development, increasing revenue, or creating jobs. DHS thus adopts the common meaning of the term "entrepreneur," which embodies the concept of active, material participation by an individual in the operations and growth of a new business entity. *See* Black's Law Dictionary (9th ed. 2009) (defining "entrepreneur" as "[o]ne who initiates and assumes the financial risks of a new enterprise and who usually undertakes its management"). Whether an applicant has an "active and central role" will be determined based on the totality of the evidence provided.

The ownership criterion proposed by DHS in this rule is also essential for connecting the individual to the start-up entity providing the significant public benefit. DHS has determined that a minimum 15 percent ownership interest is a reasonable threshold for seeking parole under this rule. DHS recognizes that entrepreneurs may possess larger equity stakes in the start-up entity at the time of formation or during initial seed rounds of financing (often ranging from 50–100 percent).[28] This equity stake, however, may be diluted significantly during financing rounds, or by the provision of equity compensation to key personnel within the entity. DHS further recognizes that start-up entities are not limited to one entrepreneur, and that there may be instances when a team of entrepreneurs will form the start-up entity. The specific equity stake by the entrepreneur in the start-up entity will therefore vary based on the particular facts and circumstances of each case. DHS thus believes establishing a minimum 15 percent threshold with respect to ownership adequately accounts for the possibility of equity dilution for the reasons described above, while ensuring that the individual continues to have a substantial ownership interest in, and assumes more than a nominal financial risk related to, the entity.

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[27] Erik Hurst & Benjamin Wild Pugsley, "What Do Small Businesses Do?" (Aug. 2011), *available at http://www.brookings.edu/~/media/files/programs/es/bpea/2011_fall_bpea_papers/2011_fall_bpea_conference_hurst.pdf.*

[28] "Venture Capital," Encyclopedia of Small Business, 2007. Retrieved September 22, 2015 from Encyclopedia.com: *http://www.encyclopedia.com/doc/1G2–2687200596.html* ("The percentage of equity ownership required by a venture capital firm can range from 10 percent to 80 percent, depending on the amount of capital provided and the anticipated return. But most venture capital organizations want to secure equity in the 30–50 percent range so that the small business owners still have an incentive to grow the business. Since venture capital is in effect an investment in a small business' management team, the venture capitalists usually want to leave management with some control.").

DHS anticipates that an applicant would be able to demonstrate sufficient satisfaction of the above criteria by providing various forms of evidence. With respect to ownership, DHS anticipates that an applicant would be able to provide copies of legal or financial documents—such as formation and organizational documents, equity certificates, equity ledgers, ownership schedules, or capitalization tables—indicating the applicant's ownership interest in the start-up entity. With respect to the applicant's role within the entity, DHS expects that an applicant would provide supporting documentation of his or her role within the entity, as well as the knowledge and experience that is central to the entity's business. Such supporting documentation may include:

- Letters from relevant government agencies, qualified investors, or established business associations with an understanding of the applicant's knowledge, skills or experience that would advance the entity's business;
- newspaper articles or other similar evidence that the applicant has received significant attention and recognition;
- evidence that the applicant or entity has been recently invited to participate in, is currently participating in, or has graduated from one or more established and reputable start-up accelerators;
- evidence that the applicant has played an active and central role in the success of prior start-up entities;
- degrees or other documentation indicating that the applicant has knowledge, skills, or experience that would significantly advance the entity's business; and
- any other relevant, probative, and credible evidence indicating the applicant's ability to advance the entity's business in the United States.

DHS welcomes public comments on all aspects of these standards, including the definition of the term "entrepreneur." DHS also welcomes comment on the types of evidence that may be considered when determining whether an applicant is an entrepreneur, including alternative suggestions on how applicants may be able to demonstrate eligibility.

3. Capital Investment or Government Funding Criteria

DHS is also proposing that an individual who seeks parole under this rule must validate the entity's substantial potential for rapid growth and job creation by providing additional reliable evidence of such potential. DHS is proposing that this requirement may generally be satisfied by demonstrating that the entity has: (1) Received substantial investment of capital from U.S. investors with established records of successful investments; or (2) received substantial awards or grants for purposes of economic development, research and development, or job creation from Federal, State, or local government entities that regularly provide such awards or grants to U.S. businesses. *See* proposed 8 CFR 212.19(b)(2)(ii)(B). DHS further proposes alternative criteria under which an applicant who partially meets one or more of these two criteria may be considered for parole under this rule if he or she provides additional reliable and compelling evidence that his or her parole would provide a significant public benefit. *See* proposed 8 CFR 212.19(b)(2)(iii).

These investment and funding criteria are proposed to serve as reliable indicators of an entity's substantial potential for rapid growth and job creation and, ultimately, of the significant public benefit that a grant of parole would provide in an individual case. Meeting these criteria, however, is intended to supplement—and not supplant—the need to provide other supporting evidence (such as that described in section IV.B.1) establishing that the applicant meets the general criteria for a grant of parole under the proposed rule. Even if an entity meets the investment or funding criteria discussed herein, additional evidence would generally assist USCIS officers in determining whether an applicant has met the required standard for parole and merits a favorable exercise of discretion. Among other things, such supplementary evidence may: provide additional external validation of the start-up entity (*e.g.,* receiving additional funding from a government entity, being accepted into a start-up accelerator, generating significant revenue, or creating jobs); show that the entity works in fields important to economic growth (*e.g.,* creating new technologies or engaging in cutting-edge research); or demonstrate that the entrepreneur has knowledge, skills, or experience that would substantially advance the entity's business (*e.g.,* successfully leading prior start-up entities, having advanced degrees in the appropriate field, or establishing critical patents). DHS also anticipates that such additional evidence would be available in the majority of cases involving recently formed entities that have substantial potential for growth and that otherwise meet the standards proposed in this rulemaking.

a. Substantial Investment From Qualified U.S. Investors

DHS proposes to allow an applicant to demonstrate his or her entity's substantial potential for rapid growth and job creation by showing that the entity has received substantial investment of capital from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of successful investments in start-up entities. *See* proposed 8 CFR 212.19(b)(2)(ii)(B). DHS proposes that investments may generally be considered "substantial" with respect to an initial application for entrepreneur parole if total investments, which can be from one or more qualified U.S. investors, meet or exceed $345,000. *Id.* DHS further proposes that qualifying investors include only those investors who have a history of making similar or greater investments on a regular basis over the last 5 years and who can demonstrate that at least two of the entities receiving such investments have subsequently experienced significant growth in revenue or job creation. *See* proposed 8 CFR 212.19(a)(5). DHS believes that the investment of a substantial amount of capital by qualified investors in an entrepreneur's start-up entity may serve as a strong indication of an entity's potential to positively impact the U.S. economy and labor force.

DHS is proposing a general qualified investment threshold of $345,000, which DHS believes is a reasonable minimum investment amount that will serve as a reliable external validation factor by qualified investors.[29] DHS

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[29] The $345,000 figure is rounded from the actual figure $345,390, which is the 2015 average for all angel investments (the largest source of start-up capital for innovative firms) received by start-up entities. *See* Jeffrey Sohl, "The Angel Investor Market in 2015: A Buyers' Market," Center for Venture Research, May 25, 2015, available at: *https://paulcollege.unh.edu/sites/paulcollege.unh.edu/files/webform/Full%20Year%202015%20Analysis%20Report.pdf.* The rounded $345,000 figure from 2015 is also very close to the $342,000 grand mean for the period

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reached this figure after analyzing available data on angel investments—the largest source of start-up capital for innovative firms—as well as initial or "seed" round investments from venture capital firms and start-up accelerators.[30] DHS also analyzed other available data on capital amounts used to create new businesses, and consulted with the Small Business Administration (SBA). In determining a minimum investment amount applicable to all qualified investors (*e.g.*, venture capital firms,[31] angel investors,[32] and start-up accelerators [33]), the $345,000 amount is generally on par with, based on data that DHS reviewed, the combined capital investment typically obtained in early rounds of investment from venture capital firms or angel investors.[34]

DHS is also proposing a requirement that the substantial investment be received within the 365 days immediately preceding the filing of the application for initial parole. In addition to addressing potential fraud concerns, this requirement assists in validating the entity's substantial potential for rapid growth and job creation and, ultimately, of the significant public benefit that a grant of parole to the entrepreneur would provide. This requirement ensures that a qualified investor or government entity has recently validated (within 365 days) the start-up entity's potential for rapid growth and job creation. However, DHS recognizes that start-up investment is a rapidly evolving field, and welcomes additional feedback, including data on trends in investment that may be available, as such feedback and data may impact the minimum investment threshold in the Department's final rule.

As noted above, in order to meet the investment criteria for consideration of parole under this proposed rule, the $345,000 total investment must be made by one or more qualified U.S. investors. *See* proposed 8 CFR 212.19(a)(5) and (b)(2)(ii)(B)(*1*). DHS proposes to define "qualified investor" as either an individual or an organization. *See* proposed 8 CFR 212.19(a)(5). If the investor is an individual, the investor would need to be a U.S. citizen or lawful permanent resident. *Id.* If the investor is an organization, the investor would need to be located in the United States and operate through a legal entity organized under the laws of the United States that is majority owned and controlled, directly or indirectly, by U.S. citizens or lawful permanent residents. *Id.* In either case, such investor could not have been permanently or temporarily enjoined from participating in the offer or sale of a security or in the provision of services as an investment adviser, broker, dealer, municipal securities dealer, government securities broker, government securities dealer, bank, transfer agent or credit rating agency, barred from association with any entity involved in the offer or sale of securities or provision of such services, or otherwise found to have participated in the offer or sale of securities or provision of such services in violation of law. *See* proposed 8 CFR 212.19(a)(5).

In addition, DHS proposes to limit qualifying investors to those who have an established record of successful investments in start-up entities. DHS proposes that such a record would include, during the 5-year period prior to the date of filing of the parole application, 1 or more investments in other start-up entities in at least 3 separate calendar years in exchange for equity or convertible debt comprising a total of no less than $1,000,000.[35] *See* proposed 8 CFR 212.19(a)(5)(i). DHS will require monetary commitments, rather than non-monetary commitments such as credit for in-kind value (*e.g.*, credit for services), given the difficulty of valuing such commitments and the potential for fraud and abuse. The applicant would also need to show that, subsequent to such investment by the investor, at least 2 such entities each created at least 5 qualified jobs or achieved at least $500,000 in revenue with average annualized revenue growth of at least 20 percent. *See* proposed 8 CFR 212.19(a)(5)(ii).

These criteria are intended to ensure that investors are bona fide, and thus to prevent fraud and protect the integrity of the parole process under this rule. They are also intended to ensure that a qualifying investment serves as a strong and reliable indication of the start-up entity's substantial potential for rapid growth and job creation. By requiring an investor to have a track record of investing substantial funds in start-up entities that subsequently achieve significant revenue and job creation, these provisions would enhance the Department's ability to have confidence in the investments made by qualified investors as reliable validation of a start-up entity's potential. At the same time, the criteria would mitigate potential misuse of the parole process, including by individuals or entities that may claim to be bona fide investors to conceal fraud or other illicit activity. DHS expects that individuals and entities that meet these criteria would include existing and bona fide start-up investors that are known to operate successfully in the business community—including established venture capital firms, angel investors, and start-up accelerators.

Finally, DHS proposes to limit "qualified investments" under this rule to investments of lawfully derived capital in start-up entities through the purchase of equity or convertible debt issued by such entities. *See* proposed 8 CFR 212.19(a)(4). DHS proposes that a qualified investment would not include an investment from: (1) The entrepreneur him or herself; (2) the

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2012–2015, *id.*, and it is corroborated by other sources. For example, according to a report from the business Web site Fundable, which specializes in startup finance, the average angel-financed firm receives approximately $333,000 in angel capital. This report can be found at: *https://www.fundable.com/learn/resources/guides/investor-guide/types-of-investors.*

[30] DHS is aware that there is a wide range of investment amounts for angel, venture, and accelerator investment applied to startups. For example, DHS analysis of data from SeedDB reveals that some large accelerators provide initial investments of less than $100,000. DHS analysis reveals that angel investments that are conducted in groups, or that are co-invested with venture or other institutional investors, have ranged from about $350,000 to $725,000 since 2013, with an up-trend over the last two years, and several data sources reveal medians of about $500,000. Seed and startup venture investments are generally over $1,000,000. DHS believes that the $345,000 angel average for 2015 is reasonable because it represents nearly a mid-point across the various data and sources DHS has reviewed for such investments, is publicly available from a reputable source, and includes all angel investments. Additional details on the Seed DB accelerators data are found in Section C, "An Alternative Estimate of Entrepreneurs Based on Investment Structures," in the ensuing "Statutory and Regulatory Requirements" section of this notice. Mean and median figures for venture backed and angel group can be found in the following sources: *http://www.ey.com/Publication/vwLUAssets/Venture_Capital_Insights_4Q14_-_January_2015/$FILE/ey-venture-capital-insights-4Q14.pdf; http://www.angelresourceinstitute.org/~/media/Files/Halo%20Report%202015%20Annual%20vFinal.pdf; and http://www.inc.com/linkedin/tomasz-tunguz/inflation-deflation-startup-fundraising-market-tomasz-tunguz.html.*

[31] Government, semi-government, or private firm that provides startup or growth equity capital and/or loan capital to promising ventures for returns that are higher than market interest rates. *See http://www.businessdictionary.com/definition/venture-capital-firm.html.*

[32] Business "angels" are high net worth individual investors who seek high returns through private investments in start-up companies. *See https://www.sba.gov/content/venture-capital#AngelInvestors.*

[33] Business entities that make seed-stage investments in promising companies in exchange for equity as part of a fixed-term, cohort-based program, including mentorship and educational components, that culminates in a public pitch event or demo day. *See https://www.sba.gov/advocacy/innovation-accelerators-defining-characteristics-among-startup-assistance-organizations.*

[34] *See* note 29.

[35] "Venture Capital," Encyclopedia of Small Business, 2007. Retrieved September 22, 2015 from Encyclopedia.com: *http://www.encyclopedia.com/doc/1G2-2687200596.html* ("Most venture capital firms look for investment opportunities in the $250,000 to $2 million range.")

parents, spouse, brother, sister, son, or daughter of such entrepreneur; or (3) any corporation, limited liability company, partnership, or other entity in which such entrepreneur or the parents, spouse, brother, sister, son, or daughter of such entrepreneur directly or indirectly has any ownership interest. *Id.* DHS is proposing these exclusions to help ensure that the qualified investment was acquired through an arms-length transaction and is a bona fide investment. Any investment that does not meet the definition of "qualified investment" will not count toward the criteria to meet the proposed rule's minimum investment threshold.

DHS welcomes comments on all aspects of this section, including the proposed investment threshold, any potential alternative amounts for that threshold, and additional data. For comments recommending investment threshold amounts, the Department requests that commenters provide rationales and data, if available, to support their recommendations.

b. Substantial Government Awards or Grants

DHS proposes that an applicant may alternatively demonstrate a start-up entity's substantial potential for rapid growth and job creation by showing that the entity has received significant funding in the form of awards or grants from Federal, State or local government entities. DHS proposes that to satisfy this criterion, the awards or grants generally would need to be made by one or more Federal, State, or local government entities that regularly provide such funding to U.S. businesses for economic development, innovation, research and development, or job creation reasons. DHS proposes to exclude any contractual commitment for goods or services, including any contracts that might appear to be, or could be made to look like, an award or grant. DHS believes this exclusion is reasonable since a contract for goods and services with a Federal, State or local government entity would typically provide a direct benefit to that government entity and not a public benefit, such as encouraging economic development and innovation, that an award or grant would provide as required by this proposed rule. *See* proposed 8 CFR 212.19(a)(3). DHS also proposes that to be considered substantial, such awards or grants generally would need to total $100,000 or more. *See* proposed 8 CFR 212.19(b)(2)(ii)(B)(*2*).

In the United States today, a range of Federal, State, and local government entities, including State or local economic development corporations (EDCs), evaluate U.S. businesses and provide awards or grants when such funding is deemed to be in the public interest.[36] DHS believes that significant funding from such a government entity is a strong indicator of a start-up entity's substantial potential for rapid growth, including through enhancing innovation, generating revenue, obtaining significant additional investments of capital, and creating jobs. Because such government entities regularly evaluate the potential of U.S. businesses, the choice to provide a significant award or grant to a particular start-up entity is generally a compelling indicator of that start-up's substantial potential for growth and job creation. Additionally, because government entities are by definition formed to serve the public, the choice by such an entity to fund a particular business generally indicates the government entity's independent assessment that the business's operations would provide a significant public benefit. For these reasons, DHS believes it is reasonable to establish a lower threshold amount for government funding in comparison to the previously discussed threshold amount for private investment. DHS proposes a general $100,000 minimum government funding threshold based on the above and the fact that seed capital awards ("Phase I" awards) from the Small Business Innovation Research (SBIR) program are generally below $150,000.[37]

DHS welcomes comments on all aspects of this section, including the proposed government funding threshold, any potential alternative amounts for that threshold, and additional data. For comments recommending government funding threshold amounts, the Department requests that commenters provide rationales and data, if available, to support their recommendations.

c. Alternative Criteria for Parole Consideration

Additionally, DHS proposes that an applicant who only partially meets one or both of the above investment or government funding sub-criteria for parole under this rule may still be considered for parole under this rule in certain limited circumstances. *See* proposed 8 CFR 212.19(b)(2)(iii). Specifically, DHS would consider parole for such an applicant if the applicant provides additional "reliable and compelling" evidence of the entity's substantial potential for rapid growth and job creation. *See* proposed 8 CFR 212.19(b)(2)(iii). Importantly, such parole would not be available to applicants who are unable to demonstrate that their start-up entities have received a substantial amount of U.S. capital investment or government funding. Rather, the applicant would need to show as a preliminary matter that his or her entity has received a substantial level of capital investment or government funding, although less than $345,000 or $100,000, respectively. The applicant would also need to further validate the entity's substantial potential for rapid growth and job creation by submitting additional evidence that DHS determines to be both reliable and compelling. DHS proposes that such evidence be reliable and compelling in its own right to overcome the applicant's inability to fully meet the threshold criteria otherwise required under the proposed rule.

DHS is not proposing to define the specific types of evidence that may be deemed "reliable and compelling" at this time, as the Department seeks to retain flexibility as to the kinds of supporting evidence that may warrant the Secretary's exercise of discretion in granting parole based on significant public benefit. But DHS believes that to meet the parole standard in this context without meeting the threshold criteria, such additional evidence would need to be particularly persuasive. In other words, although all applicants for entrepreneur parole would be expected to provide supplementary evidence indicating that their parole would serve a significant public benefit, applicants who only partially meet the threshold criteria mentioned above would need to provide other reliable and compelling evidence to ensure that the totality of the evidence demonstrates that the start-up entity has the substantial potential for rapid growth and job creation.

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[36] *See, e.g.*, U.S. Small Business Administration, *https://www.sbir.gov* (describing Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which provide early-stage capital for innovative small companies in the United States) and National Institutes of Health, *https://sbir.nih.gov/* (describing healthcare opportunities under SBIR and STTR); U.S. Economic Development Association (EDA), Regional Innovation Strategies Program (RIS), *http://www.eda.gov/oie/ris/* (providing grants to cities and local EDCs, among others, to fund startups); Energy Innovations Small Grant Program, *www.energy.ca.gov/research/innovations* (providing State grants of up to $150,000 to small businesses, among others, to research innovative energy concepts); Startup Philadelphia Call for Ideas, *http://www.startupphl.com/startup-phl-call-for-ideas* (partnership between City of Philadelphia and the Philadelphia Industrial Development Corporation to provide $500,000 to grow the startup and early-stage business economy in Philadelphia).

[37] The Small Business Innovation Research (SBIR) program is coordinated by the Small Business Administration to seed capital for start-up businesses. It is designed to stimulate technological innovation among small private-sector businesses and encourages small businesses to market the SBIR technology in the private sector. It is the largest source of seed capital in the United States for technology driven start-ups, funding between 5,000 and 7,000 projects a year. The "first phase" award is an innovation grant made for initial eligibility and corresponds to the start-up of the commercial business and proof of "concept phase"—the average award amounts vary by department, but most SBIR Phase I awards are made at or below $150,000. The Phase I awards are geared towards financing the startup of the private commercial entity and also the innovation and research and development (R&D) that the enterprise undertakes.

DHS anticipates that the necessary amount and requisite evidentiary weight of such additional evidence would depend on the degree to which an applicant meets one or both of the threshold sub-criteria related to capital investment or government funding. For example, an applicant whose entity has received $200,000 in qualifying capital investment would be expected to provide more validating evidence than an applicant whose entity received $300,000 in such investment. Moreover, DHS may give particular weight to evidence that tends to serve as a strong validation of the entity's substantial potential for rapid growth and job creation. For example, evidence that an entity has been selected to participate in, is participating in, or has graduated from one or more established and reputable start-up accelerators (or incubators) may serve as, depending on the accelerator's success rate and other factors, a strong indicator of the entity's potential. With respect to start-up accelerators, DHS expects to evaluate them on several relevant factors, including years in existence, graduation rates, significant exits by portfolio start-ups, significant investment or fundraising by portfolio start-ups, and valuation of portfolio start-ups.

Ultimately, the USCIS adjudicator would be required to determine whether such additional evidence—in conjunction with the entity's substantial capital investment or government funding, among other factors—is sufficient to establish that the applicant's parole into the United States will provide a significant public benefit (and that the applicant merits a favorable exercise of discretion). This approach is consistent with the discretionary nature of the Secretary's statutory parole authority and the fact that each parole request will be adjudicated, on a case-by-case basis, after considering the particularized facts of each case. DHS invites public comment on the types of reliable and compelling evidence that may warrant a discretionary grant of parole in such cases.

As noted above, DHS also invites public comment on alternatives to the proposed investment amount and government funding thresholds that applicants may use to demonstrate a start-up entity's substantial potential for rapid growth and job creation and that may serve as a principal basis for seeking parole under this rule. Commenters are invited to submit comments on whether significant revenue generation, participation in established and reputable start-up accelerators, or any other significant external validation factor should be included as a principal basis for seeking parole under this rule. DHS specifically invites comment on whether applicants can adequately demonstrate the future substantial potential for rapid growth and job creation through established records of revenue generation, revenue growth, job creation, or any combination of these and other factors. Commenters should recommend threshold levels for obtaining parole under suggested criteria, data to support the recommended alternative thresholds, and the types of reliable evidence that applicants may submit to substantiate their claims. Comments should include any relevant data to substantiate recommendations, if available.

C. Application Requirements for Initial Period of Parole

1. Filing the Application for Entrepreneur Parole (Form I–941)

DHS is proposing to establish new application requirements for entrepreneurs seeking parole under this rule. Prior to appearing before DHS as an applicant for admission requesting parole, entrepreneurs would be required to file with USCIS an Application for Entrepreneur Parole (Form I–941 or successor form), established by this rulemaking, along with supporting documentation. This application is designed to capture information pertaining to the criteria that are specific to parole requests filed under this rule. USCIS would accept Applications for Entrepreneur Parole filed from within the United States or outside the United States. DHS is proposing an application filing fee of $1200. *See* proposed 8 CFR 103.7(b)(1)(i)(FFF). In addition to filing the application, supporting documentation, and filing fee, applicants would be required to submit a biometric services fee as prescribed by 8 CFR 103.7(b)(1)(i)(C).

2. Requirement To Appear for Submission of Biometric Information

DHS proposes that all individuals filing the Application for Entrepreneur Parole would be required to appear for collection of their biometric information, including fingerprints and photographs. *See* proposed 8 CFR 212.19(e). DHS is proposing a biometric collection requirement so that background checks can be completed for each applicant, and so that any necessary travel documents can be produced. As noted above, applicants would be required to pay the fee for biometric services at the time of filing the Application for Entrepreneur Parole.

As is currently the case for other applicants for parole, the location for the collection of biometric information will depend on whether the applicant filed the application from within the United States or outside the United States. *See* form instructions to Application for Entrepreneur Parole (Form I–941). Applicants applying from within the United States will be required to appear at a USCIS Application Support Center (ASC) for submission of biometrics. Applicants applying from outside the United States may be required to appear at an overseas USCIS office. Applicants who will be receiving their travel documents overseas from a Department of State Consulate (or Embassy) will have their biometrics taken after their parole is authorized, but before their travel document is issued. Under current DHS regulations, DHS may determine that an application has been abandoned and thus should be denied if the applicant fails to appear at the biometrics appointment or otherwise fails to provide required biometric information. *See* 8 CFR 103.2(b)(13)(ii).

3. Income-Related Condition on Parole

Under the process proposed by this rule, DHS would consider granting parole to individuals whose enterprises have the substantial potential for rapid growth and job creation, including through the development of new technologies or the pursuit of cutting-edge research. To further ensure this is the case, and in addition to the high threshold criteria discussed above, DHS is proposing that an individual who is paroled into the United States under this rule must, as a condition of that parole, maintain household income while in the United States that is greater than 400 percent of the Federal poverty line for his or her household size as defined by the Department of Health and Human Services (HHS). *See* proposed 8 CFR 212.19(i). DHS is further proposing to require the applicant to attest, as part of the Application for Entrepreneur Parole, that he or she will maintain household income at this level as a condition of parole and to provide evidence that he or she satisfied this condition if applying for re-parole. *Id.*

This income threshold is intended to establish that applicants seeking parole under this rule will have sufficient personal economic stability so as to better ensure that they will make significant economic and related contributions to the United States. The income threshold and time limits on parole also mean that individuals eligible for parole under this rule would generally not be eligible for Federal public benefits or premium tax credits under the Health Insurance Marketplace of the Affordable Care Act.[38] Under the proposed rule, DHS would be authorized to terminate parole for any individual who fails to maintain the threshold income level. *See* proposed new 8 CFR 212.19(k)(3)(iv). DHS would request verification of the parolee's household income when the parolee applies for re-parole, if applicable, or subsequent to any material change notification submitted by the parolee to USCIS.

DHS welcomes comment on the proposed income threshold.

4. Adjudication of Applications

When adjudicating the Application for Entrepreneur Parole, DHS is proposing that USCIS will examine whether the entrepreneur has demonstrated, through credible and probative evidence, that he or she warrants a favorable exercise of the Secretary's discretion. *See* proposed new 8 CFR 212.19(d)(1). If the entrepreneur meets the criteria for parole under the proposed rule, and a favorable exercise of discretion is warranted, USCIS may approve the request for parole. *Id.* Moreover, in determining whether an individual applicant's parole would provide a significant public benefit and whether to favorably exercise the Secretary's discretion in that individual case, USCIS will consider and weigh all evidence, including any derogatory evidence or information, such as but not limited to evidence of criminal history or other adverse factors. *Id.*

If USCIS, in its discretion, determines that the applicant does not warrant a grant of parole under the proposed rule, it may deny the application. *See* proposed 8 CFR 212.19(b) and (c). DHS is also proposing that there would be no right of appeal following a decision to deny entrepreneur parole, just as is the case currently with other parole requests. *See* proposed 8 CFR 212.19(d)(4). DHS is also proposing that applicants be precluded from filing motions to reopen or reconsideration under 8 CFR 103.5(a)(1). *Id.*

DHS, however, proposes to retain its authority and discretion to reopen or reconsider a decision only on its own motion. *See* proposed 8 CFR 212.19(d)(4). For the parole process proposed in this rulemaking, DHS may, in its discretion, reopen a decision and deny or approve parole at any time if DHS finds that the decision was issued in error. If USCIS determines that approval of an Application for Entrepreneur Parole was made in error, parole may be revoked. DHS would follow the requirements of 8 CFR 103.5(a)(5) before reopening a case and denying a parole application.

Because the determination to grant or deny a request for parole is a discretionary determination, the parole process proposed in this rule may not be relied upon to create any right or benefit, substantive or procedural, enforceable at law or by any individual or other party in removal proceedings, in litigation with the United States, or in any other form or manner. Parole determinations would continue to be discretionary, case-by-case determinations made by DHS, and parole may be revoked or terminated at any time. Parolees under this proposal would assume sole risk for any and all costs, expenses, opportunity costs, and any other potential liability resulting from a revocation or termination of parole. A grant of parole would in no way create any reliance or due process interest in obtaining or maintaining parole or being able to remain in the United States to continue to direct a start-up entity or for other reasons.

5. Limitation on Number of Entrepreneur Parolees per Start-Up Entity

DHS proposes to limit the number of entrepreneurs who may be granted parole under this rule with the same start-up entity. DHS recognizes that a start-up entity may be developed by more than one entrepreneur. DHS also believes that it would be difficult for a large number of entrepreneurs associated with the same start-up entity to each meet the proposed criteria and comply with the proposed conditions while ultimately developing a successful business in the United States. DHS therefore believes that imposing a limit on the number of entrepreneurs who may be granted parole based on the same start-up entity is consistent with ensuring that each entrepreneur's parole will provide a significant public benefit. Specifically, DHS is proposing that parole may be granted to no more than 3 entrepreneurs per start-up entity. *See* proposed 8 CFR 212.19(f).

This limitation is intended to strengthen the integrity of the proposed entrepreneur parole process in various ways. Among other things, limiting the number of individuals who may be granted parole under this rule with respect to the same start-up entity will be an additional means of preventing an entity from being used as a means to fraudulently allow individuals to enter the United States. Such a limit, for example, diminishes the incentive to dilute equity in the start-up entity as a means to fraudulently acquire parole for individuals who are not bona fide entrepreneurs. Such a limit will also help ensure that the tangible benefits that may flow from the start-up entity's success in the United States—such as rapid revenue generation and job creation—are more likely to inure to the United States and its workers. Relatedly, DHS is concerned that a higher number of entrepreneurs associated with the same start-up entity may affect the start-up's ability to grow and succeed, and may even result in the startup's failure, thus preventing the goals of the proposed parole process.[39] To facilitate this determination, DHS is proposing to require an applicant to provide information on the application about any other individuals who have applied for or been granted parole based on the same start-up entity.

DHS welcomes comments on the proposed limitation on the number of entrepreneurs who can qualify for parole under this rule with the same start-up entity, including alternative proposals.

6. Authorized Period for Initial Grant of Entrepreneur Parole

DHS proposes that applicants who are granted entrepreneur parole may be authorized for an initial parole period of up to 2 years. *See* proposed new 8 CFR 212.19(d)(2). DHS has determined that entrepreneurs paroled under this rule may need up to a 2-year period of parole initially to allow them sufficient time to develop their start-up entity, which would be at an early stage of development, and achieve rapid growth in terms of revenue generation and job creation. DHS further believes that an initial period of parole of up to 2 years, followed by one possible period of re-parole of up to 3 additional years as described below, is consistent with the amount of time successful start-up entities generally require to realize growth potential. An entrepreneur of a start-up entity that is almost 3 years old when the parole application is filed would have the possibility to obtain up to 5 years of parole, which would allow the entity to realize its growth potential by the time it is 8 years old.[40] As proposed, DHS retains the discretion to provide any length of parole to an applicant, including a period shorter than 2 or 3 years where appropriate. Moreover, although USCIS would designate an appropriate initial parole validity period upon approval of the Application for Entrepreneur Parole, CBP would retain the authority to deny parole to an applicant or to modify the length of parole authorized by USCIS upon issuing parole at the port of entry, consistent with CBP's discretion with respect to any advance authorization of parole by USCIS. DHS will issue a multiple entry travel document for individuals granted parole under this rule to permit travel during their parole validity period.

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[38] Although individuals who are granted parole for more than one year become "qualified aliens" for the purpose of applying for such benefits, *see* 8 U.S.C. 1641(b), such individuals must generally be "qualified aliens" for at least 5 years before becoming eligible for those benefits, *see* 8 U.S.C. 1613. Individuals paroled under this rule will thus generally not qualify for such benefits.

[39] Scaling Startup Genome Report: premature scaling v 1.2 (edited March 2012). Copyright 2011, Startup Genome Report Extra on Premature, Max Marmer, CSO Startup Genome, Bjoern Lasse Herrmann, CEO Startup Genome, Ertan Dogrultan, CTO Startup Genome, Ron Berman, Ph.D. at UC Berkeley (explaining that "hiring too many people too early" in a start-up's development is one of several reasons that most start-ups fail) available at *https://s3.amazonaws.com/startupcompass-public/StartupGenomeReport2_Why_Startups_Fail_v2.pdf.*

DHS welcomes public comment on the proposed limits on the duration of parole under this rule and any relevant data to support alternative durations of parole.

7. Spouses and Minor Children

DHS proposes that the spouse and children[41] of an entrepreneur granted parole under this proposed rule may also be granted parole for the same period as the entrepreneur. *See* proposed new 8 CFR 212.19(h)(2). To be paroled with (or later join) the entrepreneur, his or her spouse and children would each be required to file an Application for Travel Document (Form I–131) in accordance with the form instructions. Each spouse or child seeking parole must independently establish eligibility for parole based on significant public benefit (or, alternatively, for urgent humanitarian reasons), and that the individual merits a favorable exercise of discretion. In a case in which an entrepreneur has been granted parole based on significant public benefit under this rule, USCIS may consider granting parole to the entrepreneur's spouse and children, if any, to maintain family unity and thereby further encourage the entrepreneur to operate and grow his or her business in the United States. As with the entrepreneur, certain biometric information for each spouse and child must be included on the application, along with a biometric services fee for each dependent. If the spouse and children are in the United States, they would also be required to appear at a USCIS office within the United States. If the applicants are outside the United States, the collection of additional biometric information (fingerprints and photographs) will take place prior to travel document issuance rather than before the parole applications are adjudicated. In such cases, however, USCIS would conduct preliminary background checks on each accompanying or joining family member prior to making its discretionary determination on their parole applications.

DHS is proposing to consider granting parole to the spouses and children of entrepreneur parolees to further the central purpose of the rulemaking—encouraging foreign entrepreneurs to come to and remain in the United States to develop and grow their start-up entities and provide the benefits of such growth to the United States. DHS retains the authority to decide whether to grant parole to such spouses and children on a case-by-case basis and may determine that such individuals do not warrant parole (or re-parole) either because their parole would not be justified on significant public benefit grounds or as a matter of discretion.

D. Employment Authorization

1. Employment Authorization Incident to Parole With a Specific Employer

DHS is proposing that an entrepreneur who is paroled into the United States under this rule would be authorized for employment incident to his or her parole with the start-up entity. *See* proposed new 8 CFR 212.19(g). Under the proposed rule, the entrepreneur parolee's employment authorization would be limited to the specific start-up entity listed on the Application for Entrepreneur Parole. This limitation is intended to keep the scope of employment authorization within the purposes for which parole was granted. As the purpose of this proposed rule is to encourage foreign entrepreneurs to develop and grow their start-up businesses in the United States—rather than obtain new sources of employment—DHS believes this limitation on employment authorization is a reasonable restriction.

DHS further proposes that such employment authorization be "automatic" upon the grant of parole so that the entrepreneur can pursue his or her parole-related activities with the start-up entity without delay. DHS believes that requiring entrepreneurs to file separate applications for employment authorization and wait for Employment Authorization Documents (EADs, Form I–766) before beginning work[42] would undermine the very basis for extending parole to entrepreneurs—the rapid growth and success of the start-up entity. The delay resulting from the need to apply for and receive EADs (up to 90 days or more) could be detrimental to the success of the start-up entity.

Finally, DHS is proposing several conforming amendments to 8 CFR 274a.12(b), which lists the classes of foreign nationals authorized for employment incident to status with specific employers. DHS proposes to amend the introductory paragraph of this provision, which currently refers only to employment-authorized "nonimmigrants," by adding a reference to parolees under this rule. *See* revised 8 CFR 274a.12(b). DHS also proposes to add entrepreneur parolees under this rule to the list of classes of individuals authorized only for employment with a specific employer (as opposed to open market employment). *See* proposed new 8 CFR 274a.12(b)(37). Specifically, the amendment would provide that entrepreneurs paroled under this rule would be employment authorized incident to their parole with their start-up entities, pursuant to proposed new 8 CFR 212.19(g). DHS would also assign a new code of admission for this class: "PE–1."

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[40] Estimates based on the Census Bureau Business Dynamics Statistics suggest that on average 55 percent of new firms survived after 3 years, but 80 percent of the firms that survived 3 years also made it through 5 years. Dane Stangler and Jared Konczal "Give me your entrepreneurs, your innovators: Estimating the Employment Impact of a Startup Visa", Ewing Marion Kauffman Foundation (February 2013), available at *http://www.kauffman.org/~/media/kauffman_org/research%2Oreports%20and%20covers/2013/02/startup_visa_impact_final.pdf;* "*CrunchBase Reveals: The Average Successful Startup Raises $41M, Exits at $242.9M,*" Techcrunch.com (Dec. 14, 2013), available at *http://techcrunch.com/2013/12/14/crunchbase-reveals-the-average-successful-startup-raises-41m-exits-at-242–9m/.* See also TruBridge Capitol Partners, *Why the 'Next Billion Dollar Startup' Is not Always the Next IPO,* Forbes, Apr. 15, 2015, available at *http://www.forbes.com/sites/truebridge/2015/04/15/why-next-billion-dollar-startup-not-always-next-ipo/* ("From 2001–2004, the average age of a company at its public exit was 5.4 years. . . . From 2009–2012, the average age was 7.9.").

[41] The terms "child" and "children" in this proposed rule have the same meaning as they do under section 101(b)(1) of the INA, 8 U.S.C. 1101(b)(1) (defining a child as one who is unmarried and under twenty-one years of age).

[42] This is the case with other parolees under existing regulations. *See* 8 CFR 274a.12(c)(11).

2. Employment Authorization Eligibility for Spouses

DHS is also proposing to extend eligibility for employment authorization to the accompanying spouses (but not the children) of entrepreneur parolees who have been paroled into the United States. *See* proposed new 8 CFR 212.19(h)(3). Under the proposed rule, such spouses who wish to obtain employment authorization would need to apply for an EAD pursuant to 8 CFR 274a.12(c)(34), consistent with current parole policy that allows parolees to apply for employment authorization. DHS believes that allowing spouses of entrepreneurs to apply for work authorization may alleviate a significant portion of the potential economic burdens that entrepreneurs and their families may face, such as paying for academic expenses for their children, and to ensure that they satisfy the proposed condition on their parole that they maintain household income that is greater than 400 percent of the Federal poverty line, as they grow and develop their start-up entities. Moreover, extending employment authorization to the spouse may further incentivize a foreign entrepreneur to bring a start-up entity to the United States rather than create it in another country.

DHS has proposed not to extend employment authorization to the children of entrepreneurs, as it does not view the employment of these children in the United States as a significant deciding factor for an entrepreneur considering to create and develop start-up entities with high growth potential in the United States. DHS has extended eligibility for employment authorization to minors within the following nonimmigrant categories: Dependents of Taipei Economic and Cultural Representative Office (TECRO) E–1 nonimmigrants; J–2 dependent children of J–1 exchange visitors; dependents of A–1 and A–2 foreign government officials; dependents of G–1, G–3, and G–4 international organization officials; and dependents of NATO officials. But in each of these instances, DHS has extended eligibility for employment authorization to minor children based on particular foreign policy considerations; these underlying considerations are not present in the proposed entrepreneur parole process.

3. Documentation for Employment Eligibility Verification (Form I–9)

As with other classes of aliens listed as employment authorized incident to status with a specific employer in 8 CFR 274a.12(b), entrepreneur parolees would not be issued EADs (Forms I–766) as evidence of employment authorization. Instead, DHS would issue Arrival/Departure Records (Forms I–94) with the entrepreneur's code of admission ("PE–1"), which indicates that the entrepreneur is employment-authorized incident to parole. Because the Arrival/Departure Record would contain this code, the record would be sufficient evidence of employment authorization for Employment Eligibility Verification (Form I–9) purposes.

As with other employers, the start-up entity would be required to verify the employment authorization of its employees, including the entrepreneur paroled under this rule, to comply with employment eligibility verification requirements. DHS is proposing to amend the regulations governing these requirements by adding to the list of documents acceptable by employers for completion of the Form I–9. The proposed rule would add to this list a combination of the entrepreneur's valid foreign passport and his or her Arrival/Departure Record indicating employment-authorization pursuant to parole. *See* proposed 8 CFR 274a.2(b)(1)(v)(A)(*5*).

This proposal would ensure that entrepreneur parolees under this rule will have documentation evidencing identity and employment authorization that is acceptable for meeting the Form I–9 requirements immediately upon receiving parole to the United States. Because the document combination described above (foreign passport and Arrival/Departure Record) has been acceptable for Form I–9 purposes since the Employment Eligibility Verification requirements were first established in 1987, employers should readily recognize the document combination as acceptable for such purposes.

Further, DHS is satisfied that this document combination contains sufficient security features, as required by section 274A(b)(1)(B)(ii)(III) of the INA, 8 U.S.C. 1324a(b)(1)(B)(ii)(III). An Arrival/Departure Record issued to an entrepreneur parolee will indicate the validity period for parole and the new code of admission ("PE–1") that is specific to such parolees. In addition, DHS proposes to automatically extend the employment authorization of an entrepreneur parolee whose parole has expired but who has filed a timely application for re-parole with the same start-up entity. *See* proposed 8 CFR 274a.12(b)(37). In such cases, employment authorization would be extended for a period not to exceed 240 days beginning on the date of expiration of parole. Extending work authorization in this manner would allow an entrepreneur parolee to continue working without interruption with his or her start-up entity while the application for re-parole is pending.

4. Technical Changes

DHS is proposing to revise the existing, general parolee employment eligibility provision at 8 CFR 274a.12(c)(11) to clarify that the employment eligibility of entrepreneur parolees and their spouses under this rule are governed by proposed 8 CFR 274a.12(b)(37) and 8 CFR 274a.12(c)(34) rather than 8 CFR 274a.12(c)(11). In addition, DHS is proposing to update 8 CFR 274a.12(c)(11) to replace outdated references to parole "for emergency reasons" and "reasons deemed strictly in the public interest" with the current statutory standards for parole—"urgent humanitarian reasons" and "significant public benefit." *See* INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).

E. Material Change Reporting

DHS proposes that, consistent with filing requirements for reporting material changes in other contexts (such as the requirement to submit amended petitions when there are material changes), an entrepreneur who has been granted parole under this rule would be required to immediately report to USCIS any material changes potentially affecting his or her grant of parole. *See* proposed 8 CFR 212.19(j). In cases involving one or more material changes where the entrepreneur will continue to be employed or associated with his or her start-up entity, the entrepreneur must submit a new Application for Entrepreneur Parole with fee (not including any biometric fees) to notify USCIS of the material change(s). Depending on the nature and scope of the material change(s) reported, USCIS may continue to authorize parole or seek to terminate parole. If the entrepreneur will no longer be employed or associated with the start-up entity, or if he or she ceases to possess at least a 10 percent ownership stake in the entity, the entrepreneur must immediately notify USCIS in writing of those changes. Upon receipt of such notification, USCIS would issue an automatic revocation of the entrepreneur's parole, as well as the parole of any dependents.

For purposes of this rule, DHS proposes the term "material change" to mean any change in facts that could reasonably affect the outcome of DHS's determination that the entrepreneur provides, or continues to provide, a significant public benefit to the United States. Such changes would include, but are not limited to, the following: Any criminal charge, conviction, plea of no contest, or other judicial determination in a criminal case concerning the entrepreneur or start-up entity; any complaint, settlement, judgment, or other judicial or administrative determination concerning the entrepreneur or start-up entity in a legal or administrative proceeding brought by a government entity; any settlement, judgment, or other legal determination concerning the entrepreneur or start-up entity in a legal proceeding brought by a private individual or organization involving claims for damages exceeding 10 percent of the current assets; a sale or other disposition of all or substantially all of the start-up entity's assets; the liquidation, dissolution or cessation of operations of the start-up entity; the voluntary or involuntary filing of a bankruptcy petition by or against the start-up entity; and any significant change to the entrepreneur's role in or ownership and control of the start-up entity or any other significant ownership and control change in the start-up entity. *See* proposed new 8 CFR 212.19(a)(10) and (j). Failure to timely file or otherwise comply with the material change reporting requirements may result in a denial of subsequent parole applications or revocation of parole according to proposed 8 CFR 212.19(k)(3)(ii).

DHS welcomes public comment on the proposed definition of the term "material change." DHS also welcomes comment on the types of situations that would constitute material changes.

F. Re-Parole

DHS proposes that individuals who have been granted entrepreneur parole may be eligible for one additional, successive period of re-parole of up to 3 years with the same start-up entity if such additional period of parole is determined to serve a significant public benefit. *See* proposed 8 CFR 212.19(c) and (f). An individual may thus be paroled into the United States under the proposed rule, pursuant to an initial period of parole and any period of re-parole, for a maximum period of 5 years. *See* proposed 8 CFR 212.19(f). An entrepreneur parolee seeking re-parole should request such re-parole before his or her current period of parole expires. Failure to file a request for re-parole before the expiration of the current parole period will result in an automatic termination of parole and a loss of employment authorization for the entrepreneur and any derivatives (*i.e.*, spouse and any child(ren)). *See* proposed 8 CFR 212.19(k)(2) and 8 CFR 274.12(b)(37).

As discussed above, DHS believes that a total maximum 5-year period of parole under this rule (an initial period of up to 2 years, plus one possible re-parole period of up to 3 years) is consistent with the amount of time successful start-up entities generally require to realize their growth potential. This would generally allow sufficient time for a successful start-up entity to engage in an initial public offering, or otherwise advance past the generally recognized start-up phase.[43] As also noted above, DHS would retain the discretion to provide any length of parole to an applicant, including a *cumulative* period shorter than 5 years.

DHS welcomes comments regarding the length of parole and re-parole.

1. Criteria for Re-Parole

To be considered for re-parole, an entrepreneur parolee must demonstrate that his or her stay in the United States pursuant to parole would continue to provide a significant public benefit. DHS proposes that an individual may meet this standard by demonstrating that his or her start-up entity continues to demonstrate substantial potential for rapid growth and job creation and that his or her parole would significantly help the entity continue to conduct and grow its business here. *See* proposed 8 CFR 212.19(c)(2). Because, however, the economic activity of a successful start-up entity would likely have changed since commencement of the initial parole period, DHS is proposing certain adjusted and additional criteria for granting re-parole in comparison to the criteria for initially granting parole under this proposed rule. As described further below, such changes are intended to ensure that the start-up entity continues to have substantial potential for rapid growth and job creation and, ultimately, that parole of the entrepreneur parolee continues to be justified on significant public benefit grounds.

A. Entity Continues To Be a Start-Up Entity

As noted above, the key to meriting parole under this proposed rule is the formation of an entity in the United States with the substantial potential to show rapid growth, including through increased revenue and job creation. DHS thus proposes that an applicant for re-parole show that his or her entity continues to be a "start-up entity" as that term is defined at proposed 8 CFR 212.19(a)(2). *See* proposed 8 CFR 212.19(c)(2)(ii)(A). At the re-parole stage, this would mean showing that the entity: (1) Has continued to lawfully do business during the initial period of parole, and (2) continues to have the substantial potential to experience rapid growth and job creation, including through significant revenue generation or attraction of capital investment.[44] *Id.* As discussed in section IV.B.1, the requirement for the entity to have operated lawfully in the United States during any prior period of parole is intended to ensure lawful conduct and protect the integrity of the proposed parole process under this rule. The requirement that the entity have the substantial potential to experience rapid growth and job creation is intended to capture the types of start-up entities that are most likely to meet the significant public benefit test, while excluding types of entities without such potential.

As with the application for initial parole, DHS anticipates that an applicant for re-parole would be able to meet the above criteria by submitting various forms of evidence. In addition to meeting the investment, revenue, or job creation criteria described further below, an applicant will be expected to provide supplementary evidence of the entity's continued substantial potential for rapid growth and job creation.

B. Applicant Continues To Be an Entrepreneur

To ensure that any successive grant of parole would continue to serve a significant public benefit, DHS is proposing that an applicant for re-parole show that he or she continues to meet the definition of "entrepreneur" at proposed 8 CFR 212.19(a)(1). *See* proposed 8 CFR 212.19(c)(2)(ii)(A). As discussed previously, this definition would require the applicant for re-parole to show that he or she: (1) Continues to possess a substantial ownership interest in the start-up entity, and (2) continues to serve in a central and active capacity in the entity, such that his or her knowledge, skills, or experience would continue to substantially assist the entity with the growth and success of its business. *See* proposed 8 CFR 212.19(a)(1). For purposes of seeking re-parole, the definition further provides that an individual may be considered to possess a substantial ownership interest if he or she maintains at least a 10 percent ownership stake in the start-up entity at all times during the period of parole and any subsequent period of re-parole. *Id.*

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[43] Estimates based on the Census Bureau Business Dynamics Statistics suggest that on average 55 percent of new firms survived after 3 years, but 80 percent of the firms that survived 3 years also made it through 5 years. Dane Stangler and Jared Konczal "Give me your entrepreneurs, your innovators: Estimating the Employment Impact of a Startup Visa", Ewing Marion Kauffman Foundation (February 2013), available at *http://www.kauffman.org/~/media/kauffman_org/research%2Oreports%20and%20covers/2013/02/startup_visa_impact_final.pdf*; "*CrunchBase Reveals: The Average Successful Startup Raises $41M, Exits at $242.9M,*" Techcrunch.com (Dec. 14, 2013), available at *http://techcrunch.com/2013/12/14/crunchbase-reveals-the-average-successful-startup-raises-41m-exits-at-242-9m/*. See also TruBridge Capitol Partners, *Why the 'Next Billion Dollar Startup' Is not Always the Next IPO,* Forbes, Apr. 15, 2015, available at *http://www.forbes.com/sites/truebridge/2015/04/15/why-next-billion-dollar-startup-not-always-next-ipo/* ("From 2001–2004, the average age of a company at its public exit was 5.4 years . . . . From 2009–2012, the average age was 7.9.").

[44] The entity would also need to continue to meet the definition of "U.S. business entity" at proposed 8 CFR 212.19(a)(9).

As discussed in section IV.B.2., DHS believes that the definition of "entrepreneur" proposed in this rule is essential to ensuring that granting parole in an individual case would provide a significant public benefit. By requiring an applicant for re-parole to demonstrate that he or she continues to serve in an active and central capacity and continues to have knowledge, skills, or experience integral to the entity's success, DHS is ensuring that the applicant is directly related to the entity's ability to benefit the United States, including by conducting research and development, increasing revenue, or creating jobs. Similarly, the ownership standard is also essential for connecting the individual to the start-up entity and ensuring that he or she continues to assume more than a nominal financial risk related to the entity. The reduced 10 percent equity requirement for seeking re-parole (as opposed to the 15 percent requirement for seeking initial parole) takes into account the need of some successful start-up entities to raise additional venture capital financing by selling ownership interest during their initial years of operation.

As also discussed in section IV.B.2., DHS believes that an entrepreneur seeking re-parole would be able to demonstrate sufficient satisfaction of the above criteria by providing various forms of evidence. With respect to ownership, DHS anticipates that an applicant would be able to provide copies of legal or financial documents—such as formation and organizational documents, equity certificates, equity ledgers, ownership schedules, and capitalization tables—indicating the applicant's ownership interest in the start-up entity. With respect to the applicant's role within the entity, DHS expects that an applicant could satisfy the criterion by providing evidence showing that he or she continues to serve in the same capacity as that described in the initial parole application. If the applicant has changed positions within the entity, he or she would need to provide evidence demonstrating that he or she continues to serve in a central and active capacity within the entity and that his or her knowledge, skills, or experience would continue to substantially assist the entity with the growth and success of its business.

C. Investment, Revenue, and Job Creation Criteria for Re-Parole Consideration

DHS further proposes that, to seek re-parole under this rule, an entrepreneur would need to further validate, through additional reliable evidence, the start-up entity's continued substantial potential for rapid growth and job creation. DHS is proposing that this requirement may generally be satisfied by demonstrating that the entity has: (1) Received substantial additional qualifying funding, such as awards or grants from qualifying government entities or investments of capital from U.S. investors with established records of successful investment; (2) generated substantial and rapidly increasing revenue in the United States over the prior parole period; or (3) generated a substantial number of qualified jobs for U.S. workers. *See* proposed 8 CFR 212.19(c)(2)(ii)(B). As with applications for initial parole, DHS further proposes that an applicant who partially meets one or more of these criteria for re-parole may be considered for re-parole under this rule if he or she provides additional reliable and compelling evidence that his or her re-parole would provide a significant public benefit.

i. Qualifying Funding From U.S. Investors or Government Entities

DHS proposes to allow an applicant to demonstrate that a start-up entity continues to have substantial potential for rapid growth and job creation by showing that during the preceding period of parole the entity received additional substantial qualifying funding—through "qualifying investments," "qualified government grants or awards," or a combination of both. *See* proposed 8 CFR 212.19(a)(5) and (c)(2)(ii)(B)(*1*). DHS proposes that such total investments made to the entity during the initial parole period may generally be considered "substantial" with respect to an application for re-parole if they cumulatively meet or exceed $500,000. *Id.* As with the application for initial parole, "qualifying investments" must be from established U.S. investors (such as venture capital firms, angel investors, or start-up accelerators) with a history of substantial and successful investments in start-up entities. Such qualifying investors would include only those investors who have a history of making similar or greater investments on a regular basis over the last 5 years and who can demonstrate that at least two of the entities receiving such investments have subsequently experienced significant growth in revenue and job creation. *See* proposed 8 CFR 212.19(a)(5). With respect to "qualified government grants or awards," the grants or awards generally would need to be made by one or more Federal, State, or local government entities that regularly provide such funding to U.S. businesses for economic development, innovation, research and development, or job creation reasons. *See* proposed 8 CFR 212.19(a)(3).

DHS believes that these investment criteria are reasonable for subsequent grants of parole based on consultation with the SBA, as well as the amounts of investment made in start-up entities during initial rounds of capital investment.[45] DHS believes these standards are important to ensure that the start-up entity is showing signs of success and continues to have substantial potential for rapid growth and job creation.

DHS welcomes comment on all aspects of this section, including the proposed investment threshold for re-parole and any potential alternatives to such thresholds. For comments regarding investment threshold amounts, the Department requests that commenters provide rationales and data, if available, to support their recommendations.

ii. Substantial Revenue Generation

DHS also proposes to allow an applicant to demonstrate that a start-up entity continues to have substantial potential for rapid growth and job creation by showing that the entity has exhibited rapid growth in terms of revenue generation in the United States during the relevant parole period. DHS proposes that an applicant may generally be able to meet this standard by demonstrating that the entity reached at least $500,000 in annual revenue, with at least 20 percent average annual revenue growth, during the initial parole period. *See* proposed 8 CFR 212.19(c)(2)(ii)(B)(*3*). DHS believes that these revenue criteria are reasonable and consistent with the requirement that the entity have the substantial potential for rapid growth and job creation and, ultimately, with the requirement that the entrepreneur's parole provide a significant public benefit to the United States.

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[45] *See* note 32.

Based on consultation with the SBA, DHS believes $500,000 and 20 percent annual revenue growth would be reasonable criteria for purposes of re-parole. Notably, evaluating revenue generation and growth is industry- and location-specific, and start-up entities may be at different stages of development at the time applicants file their parole requests. DHS considered proposing revenue and growth thresholds that varied by industry and geographic location, but determined that such an approach would be extremely difficult to administer. Instead, DHS decided to propose threshold criteria that would generally apply to start-up entities under this parole process. DHS chose $500,000 in revenue and 20 percent annual revenue growth as proposed threshold criteria because, after consulting with SBA, DHS determined these criteria: (1) Would be reasonable as applied across start-up entities regardless of industry or location; and (2) would serve as strong indications of an entity's potential for rapid growth and job creation (and that such entity is not, for example, a small business created for the sole or primary purpose to provide income to the owner and his or her family).

DHS's proposed revenue amount is based on analysis of available data [46] showing average revenue over a 3-year period of $215,000 for all new firms in innovative sectors. Adjusted for inflation, the average revenue of such firms is approximately $250,000. In analyzing this data, DHS applied a 20 percent growth rate, which is a high growth threshold utilized in economic and business research,[47] to the $250,000 average revenue for 2 years (the proposed length for initial parole). At a growth rate of 20 percent each year, revenue of $250,000 would grow to $360,000 over a 2-year period. DHS proposed $500,000 as the revenue criterion to take into account the fact that revenue of $360,000 represents an average for all new firms in innovative sectors and the proposed rule is aimed towards assisting high-growth startups that will provide a significant public benefit. As such, DHS believes it is appropriate to propose an amount that takes into consideration that range of industries and locations in which start-ups may conduct business, but that exceeds the average revenue for new firms, so that such an amount can serve, in combination with a 20 percent growth rate, as a reliable indicator of a start-up entity's substantial potential for continued growth and job creation. While DHS does not have reliable revenue data that is specific to high-growth startups (the revenue data available to DHS includes all new firms, including non-startups, startups, and high-growth startups), DHS believes that its analysis of available data supports the proposed $500,000 revenue criteria as a reasonable indicator of the entrepreneur's ability to continue to provide a significant public benefit to the United States.

DHS is proposing *both* a general minimum revenue threshold and a threshold percentage increase in such revenue to account for a range of start-up entities that may qualify an entrepreneur for re-parole under this rule based on revenue generation. A $500,000 minimum revenue threshold at the re-parole stage, for example, would by itself indicate little about a start-up entity that had already been generating such revenue when the application for initial parole was filed. For such an entity, the 20 percent revenue growth threshold would ensure the entity is exhibiting substantial growth and the ability to sustain substantial job creation. As noted above, 20 percent annual revenue growth is the rate used by the Department of Labor's Bureau of Labor Statistics to indicate a high rate of growth among U.S. businesses. At the same time, the 20 percent revenue growth threshold would be insufficient by itself with respect to entities that were at the lower end of the revenue generation scale when the application for initial parole was filed. For example, an entity that was generating only $250,000 in annual revenue at the time the initial parole application was filed would only require a total increase of $110,000 in annual revenue over the 2-year parole period to meet the 20 percent revenue growth threshold. For such entities, the $500,000 annual revenue threshold is intended to ensure rapid growth and the potential to sustain substantial job creation. As with the standards for initial parole, DHS believes that the above standards for re-parole: (1) Would be reasonable among start-up entities regardless of industry or location; and (2) would serve as strong indications of an entity's potential for continued rapid growth and job creation. DHS welcomes comments on the proposed revenue generation and annual revenue growth thresholds for re-parole, including any potential alternatives.

iii. Job Creation

DHS further proposes to allow an applicant to demonstrate his or her entity's substantial potential for rapid growth and job creation by showing that the entity has exhibited rapid growth in terms of job creation during the relevant parole period. DHS proposes that an applicant may generally be able to meet this standard by demonstrating that the entity created at least 10 qualified jobs with the start-up entity for U.S. workers during the initial parole period. DHS decided to require at least 10 qualified jobs for re-parole based on survey data indicating that the average employment at new businesses in 2011 was 8.7 employees.[48] DHS further believes that this job creation standard is reasonable for demonstrating a start-up entity's recent history of rapid growth and job creation.

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[46] DHS analyzed data found in the Census Bureau's Survey of Business Owner's data (SBO) set, Table SB0700CSCB10, "Statistics for All U.S. Firms by Year the Business Was Originally Established by Industry, Gender, Ethnicity, Race, and Veteran Status for the U.S.: 2007" found at: *http://www.census.gov/econ/sbo/historical.html?2007.* DHS calculated revenue per firm for the 3 years each of 2005, 2006 and 2007, which would account for "new firms" aged 3 or less since the benchmark year was 2007. To account for sectors involved mainly in innovation, DHS attempted to match sectors to those utilized in the volume projections section of the concomitant economic analysis section of the rule's regulatory impact assessment. Of those nine broad sectors, "Waste Services" is not listed separately and hence DHS utilized the other eight sectors. Because the data are arranged with two identifiers of interest, "year established" and "sector," DHS conducted an unweighted average across the 24 data points (8 sectors with 3 years each) to arrive at an average of $215,000.

[47] High-growth firms are defined by the Department of Labor's Bureau of Labor Statistics (BLS) and the Organization for Economic Cooperation (OECD) as those with at least ten employees that grow by at least 20 percent for each of 3 consecutive years based on employment. For a description of the methodology utilized to measure high-growth firms, see OECD, "*OECD-Eurostat Manual on Business Demography Statistics*" (2007), pp. 59–65, available at: *http://www.oecd.org/std/39974460.pdf.* Although the BLS and standard OECD definition applies specifically to employment, both agencies recognize that employment growth may not be a suitable measure in all cases and that valid alternative measures may be utilized. There have been a number of alternatives proposed in various peer-reviewed literature and ongoing research. For purposes of the present rule, discussion of the 20 percent growth rate in revenue, instead of employment specifically, concomitant to that DHS proposes, can be found at: Mogos, S., Davis, A. & Baptista, R. (2015), "Defining High Growth Firms. Sustainable Growth, Volatility, and Survival," Proceedings of DRUID15 Conference. June 2015, available at: *http://druid8.sit.aau.dk/acc_papers/rpq1k6cpebbhti9vh29xudqp3juy.pdf.* See also Karl Wennberg, Managing High-Growth Firms: A literature review (2013), OECD: "International Workshop on "Management and Leadership Skills in High-Growth Firms," available at: *http://www.oecd.org/cfe/leed/Wennberg_Managing%20a%20HGF.pdf.*

[48] Alicia Robb, Joseph Farhat, "An Overview of the Kauffman Firm Survey", June 2013, p. 4.

Moreover, DHS is proposing a definition for the term "qualified job" to limit the types of jobs that may be used to justify a grant of parole under this rule. *See* proposed 8 CFR 212.19(a)(6). Under the proposed rule, the term "qualified job" would mean full-time employment, as defined at the proposed 8 CFR 212.19(a)(8), located in the United States with the entrepreneur's start-up entity that has been filled for at least 1 year by one or more qualifying employees. *See* Proposed 8 CFR 212.19(a)(6). In addition, the term "qualifying employee" would mean a U.S. citizen, a lawful permanent resident, or other immigrant lawfully authorized to be employed in the United States (*e.g.*, an asylee or refugee), who is not an entrepreneur of the relevant start-up entity or the parent, spouse, brother, sister, son, or daughter of such an entrepreneur. *See* proposed 8 CFR 212.19(a)(7). For job creation to establish eligibility for a grant of parole, DHS believes it is important that the job be filled by an employee who is not closely related to an entrepreneur of the start-up entity. This limitation would mitigate the potential for fraud relating to any claimed job creation and the legitimacy of the business, and it would help to distinguish bona fide start-up entities from small businesses with limited growth potential created for the sole or primary purpose of providing income to the entrepreneurs and their families. DHS believes that merely creating jobs for the entrepreneur and the entrepreneur's family would be unlikely to provide a significant public benefit to the United States and should thus not serve as a basis for parole under this rule.

Additionally, DHS proposes that the term "full-time employment," as referenced in the proposed definition of "qualified job," would mean paid employment of an employee by the entrepreneur's start-up entity in a position that requires a minimum of 35 working hours per week. *See* proposed 8 CFR 212.19(a)(8). The Department of Labor similarly defines full time employment as requiring 35 or more hours a week.[49] Full-time employment, however, would not include combinations of part-time positions even if, when combined, such positions meet the hourly requirement per week. DHS believes that requiring that the employment include full-time remuneration would help to ensure that the entity will provide a significant public benefit to the United States and mitigates the potential for fraud as it relates to any claimed job creation and the legitimacy of the business. *See* proposed 8 CFR 212.19(a)(8).

iv. Alternative Criteria for Re-Parole Consideration

Finally, as with the application for an initial grant of parole, DHS proposes that an applicant who only partially meets one or more of the above sub-criteria related to capital investment, revenue generation, or job creation may be considered for re-parole under this rule in certain limited circumstances. *See* proposed 8 CFR 212.19(c)(2)(iii). Specifically, DHS may consider another period of parole for such an applicant if he or she provides, in addition to evidence that one or more of the sub-criteria have been partially met, "reliable and compelling" evidence of the entity's continued substantial potential for rapid growth and job creation than would be required if the applicant had fully met one or more of the above sub-criteria. *Id.* Importantly, re-parole would not be available to an applicant who fails to demonstrate any U.S. investment, revenue generation, or job creation. Rather, the applicant would need to show as a preliminary matter that the start-up entity has: (1) Received a substantial level of investment through a combination of qualifying investments and qualified government grants or awards (although less than $500,000); (2) generated a substantial level of revenue (although less than $500,000 with at least 20 percent average annual revenue growth); or (3) generated a substantial number of qualified jobs in the United States (although less than 10). The applicant would also need to demonstrate the entity's potential for rapid growth and job creation by submitting additional evidence that DHS determines to be both reliable and compelling. DHS proposes that such evidence be reliable and compelling in its own right to overcome the applicant's inability to fully meet the threshold criteria otherwise required by this rulemaking for re-parole.

As noted previously, DHS is not proposing to define the specific types of evidence that may be deemed "reliable and compelling" at this time, because DHS seeks to retain flexibility as to the kinds of supporting evidence that may warrant the Secretary's exercise of discretion in granting parole based on significant public benefit. But DHS believes that such evidence would need to be compelling to demonstrate that the entrepreneur's presence here would provide a significant public benefit considering the entity's inability to meet the otherwise applicable threshold criteria for consideration. DHS will ultimately be required to decide whether such evidence—in conjunction with the entity's substantial investment, revenue generation, or job creation—is sufficient to establish that the applicant's presence in the United States will provide a significant public benefit. This approach is consistent with the discretionary nature of the Secretary's statutory parole authority and the fact that each parole request will be adjudicated, on a case-by-case basis, after considering the particularized facts of each case.

DHS invites public comment on the level and types of reliable and compelling evidence that may warrant a discretionary grant of parole in such cases. DHS also invites public comment on alternatives to the proposed funding, revenue generation, and job creation thresholds that applicants may use to demonstrate a start-up entity's continued substantial potential for rapid growth and job creation and that may serve as a principal basis for seeking re-parole under this rule. Commenters should recommend threshold levels for obtaining re-parole under suggested criteria, along with the types of reliable evidence that applicants may submit to substantiate their claims, including any relevant data if available.

2. Application Requirements for Re-Parole

Under the proposed rule, an entrepreneur parolee seeking a period of re-parole would be required to file a request for re-parole with USCIS using the same form as for initial parole, the Application for Entrepreneur Parole (Form I–941, or successor form), and pay the same fees (filing and biometric services fees). *See* proposed new 8 CFR 212.19(c)(1). The entrepreneur would generally be required to file the request for re-parole before the expiration of the current period of parole. If the entrepreneur is in the United States at the time that USCIS approves the request for re-parole, such approval would also constitute a grant of parole. *See* proposed new 8 CFR 212.19(d)(3). An entrepreneur present in the United States in a period of parole would not be required to depart and return to the United States in order to request a new

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"While about 40 percent of firms had employees in 2004, by 2011 about 53 percent of surviving firms had employees. Surviving firms with employees, which are now in their eighth year of operations, increased average employment to 8.7 employees in 2011, up from 7.5 employees in 2010."

[49] Department of Labor Bureau of Labor Statistics, *Glossary* (last modified Feb. 28, 2008), *http://www.bls.gov/bls/glossary.htm#F.*

grant of parole from CBP at a port of entry. Along with the approval notice, USCIS would issue an electronic Arrival/Departure Record (Form I–94) reflecting the new period of parole and the code of admission assigned to entrepreneur parolees. USCIS would also issue the entrepreneur's spouse and children who have filed their own separate requests for parole, if also approved for an additional period of parole, new Arrival/Departure Records reflecting the same period of parole as the entrepreneur, but with the appropriate dependent entrepreneur parolee codes.

The entrepreneur (or spouse or dependent child), if outside the United States upon the approval of the re-parole application, would have to obtain a travel document from USCIS or DOS (*e.g.,* a boarding foil) and appear at a port of entry for CBP to make the final re-parole determination and, if granted, issue new Arrival/Departure Records. Just as with initial parole, entrepreneurs granted re-parole would be authorized to be employed by the start-up entity, incident to their parole under this proposed rule. *See* proposed 8 CFR 274a.12(b)(37). Such entrepreneurs also would be permitted to use their foreign passport in combination with their Arrival/Departure Record reflecting the new period of parole to demonstrate their identity and employment authorization for purposes of compliance with the Employment Eligibility Verification (Form I–9) requirements. *See* proposed 8 CFR 274a.2(b)(1)(v)(A)(*5*); *see also* proposed revisions to the Form I–9, Lists of Acceptable Documents.

3. Ensuring Continuous Employment Authorization

To facilitate maintenance of continuous work authorization and parole, DHS is proposing that an entrepreneur parolee may file a request for re-parole beginning 90 days prior to the expiration date of his or her current period of parole. *See* proposed Form Instructions for the Application for Entrepreneur Parole (Form I–941). To prevent potential gaps in employment authorization for entrepreneurs seeking re-parole, DHS proposes to extend automatic employment authorization to those entrepreneurs whose current parole period expires while their request for re-parole is pending. *See* proposed 8 CFR 274a.12(b)(37). DHS is proposing that this automatic employment authorization will extend for 240 days from the date the entrepreneur's initial parole period expires, or until USCIS makes a decision on the re-parole request, whichever is sooner, when a request for re-parole was timely filed by the entrepreneur. *Id.* This 240-day automatic extension of employment authorization is comparable to the extension currently provided by regulation to most nonimmigrants authorized for employment incident to status with a specific employer who have filed a request for an extension of stay with the same employer. *See* 8 CFR 274a.12(b)(20). DHS believes that a 240-day period of automatic employment authorization is equally appropriate for entrepreneur parolees and is a sufficient period of time to ensure that the entrepreneur does not experience gaps in employment authorization on account of the adjudication process. The 240-day period takes into account the complex and time-consuming adjudication required for re-parole, as well as the required biometric services appointment, which may require up to 90 days for scheduling.

G. Termination of Parole

DHS is proposing provisions governing termination of parole under this rule in cases where DHS believes such termination is appropriate, including circumstances indicating that continued parole would no longer provide a significant public benefit, pursuant to section 212(d)(5)(A) of the INA, 8 U.S.C. 1182(d)(5)(A). Consistent with DHS's parole authority, under this proposed rule DHS may, in its discretion, terminate parole granted under 8 CFR 212.19 at any time and without prior notice or opportunity to respond. Alternatively, DHS may, in its discretion, provide the entrepreneur notice and an opportunity to respond prior to terminating his or her parole under 8 CFR 212.19. In addition to the general grounds for termination of parole described at 8 CFR 212.5(e),[50] DHS is proposing the following grounds for termination of entrepreneur parole:

1. Automatic termination

DHS believes that certain circumstances warrant automatic termination of parole. In this rule, DHS proposes that parole will automatically terminate if: (a) The period of parole expires, unless the individual timely files a non-frivolous application for re-parole; or (b) USCIS receives written notice from the entrepreneur that he or she will no longer be employed by the start-up entity or ceases to possess at least a 10 percent ownership stake in the start-up entity in accordance with 8 CFR 212.19(j). *See* proposed 8 CFR 212.19(k)(2). Additionally, the parole of the spouse or child of the entrepreneur will be automatically terminated without notice if the parole of the entrepreneur has been terminated. *Id.* If a spouse whose parole is terminated also has employment authorization, the employment authorization is automatically revoked.

2. Termination on Notice

Even though DHS has the discretion to terminate parole without prior notice, USCIS will generally attempt to provide the entrepreneur or his or her spouse or children, as applicable, written notice of its intent to terminate parole if USCIS believes that: (a) The facts or information contained in the request for parole were not true and accurate; (b) the alien failed to timely file or otherwise comply with the material change reporting requirements in this section; (c) the entrepreneur is no longer employed in a central and active role by the start-up entity or ceases to possess at least a 10 percent ownership stake in the start-up entity; (d) the alien otherwise violated the terms and conditions of parole; or (e) parole was erroneously granted. *See* proposed 8 CFR 212.19(k)(3). The decision to provide notice and an opportunity to respond prior to termination of parole under 8 CFR 212.19 will be made in the discretion of DHS on a case-by-case basis.

In cases where USCIS provides written notice and an opportunity to respond, through a notice of intent to terminate, DHS is proposing to provide a period of up to 30 days for the alien's written rebuttal. *See* proposed 8 CFR 212.19(k)(4). The notice of intent to terminate would generally identify the grounds for termination of the parole and the alien may submit additional evidence in support of his or her rebuttal, when applicable. *Id.* Providing a rebuttal period of up to 30 days is generally consistent with rebuttal periods applicable to other immigration petitions and applications (*e.g.,* I–129 or I–140). If DHS nevertheless decides to terminate parole, the entrepreneur and/or his or her spouse and children are restored to the status that he or she had at the time of parole, such as being applicants for admission. *See* 8 CFR 212.5(e)(2)(i). Consistent with current parole procedures, DHS does not propose a right to appeal a decision regarding termination of parole on notice. *Id.*

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[50] The termination provisions in current parole regulations provide for termination on written notice in situations where the justification for granting parole has ended or, in the opinion of an authorized officer, neither humanitarian reasons nor public benefit warrants the continued presence of the alien in the United States. *See* 8 CFR 212.5(e)(2)(i).

If a charging document is served on the alien, the charging document will constitute written notice of termination of parole (if parole has not already been terminated), unless otherwise specified. *Id.*

In the event of a violation of one or more terms and conditions of parole solely by the spouse or a child of the entrepreneur, parole may be terminated for the violator (*i.e.,* spouse or child) without affecting the entrepreneur's parole. If a spouse whose parole is terminated also has employment authorization, the employment authorization will be revoked. 8 CFR 274a.14(b)(1)(i).

The entrepreneur and any dependents granted parole under this program will be required to depart the United States when their parole periods have expired or have otherwise been terminated, unless such individuals are otherwise eligible to lawfully remain in the United States. At any time prior to reaching the 5-year limit for parole under this proposed rule, such individuals may apply for any immigrant or nonimmigrant classification for which they may be eligible (such as classification as an O–1 nonimmigrant or lawful permanent residency through employer sponsorship). If such individuals are approved for a nonimmigrant or employment-based immigrant visa classification, they would generally be required to depart the United States and apply for a visa with DOS. As noted above, because parole is not considered an admission to the United States, parolees are unable to apply to adjust or change their status in the United States under many immigrant or nonimmigrant visa classifications.

H. Automatic Adjustment of Investment and Revenue Amount Requirements

DHS proposes that the investment and revenue amounts specified at proposed 8 CFR 212.19(a)(5), (b)(2)(ii) and (c)(2)(ii) will be automatically adjusted every 3 years by the Consumer Price Index for All Urban Consumers (CPI–U).[51] USCIS will provide notice in the **Federal Register** and on its Web site at *www.uscis.gov* prior to the beginning of the fiscal year in which the change would take effect. Investment and revenue amounts adjusted by the CPI–U will apply to all applications filed on or after the beginning of that fiscal year. DHS believes that automatically adjusting the minimum dollar amounts by the CPI–U every 3 years will maintain investment and revenue requirements at an appropriate level in relation to future economic conditions. DHS believes adjusting the minimum dollar amounts every 3 years will be more manageable operationally for DHS and less burdensome to applicants than adjustments at more frequent intervals. *See* proposed 8 CFR 212.19(l).

I. Technical Change

DHS is proposing a technical change to 8 CFR 274a.2(b)(1)(v)(C) to add the Department of State (DOS) Form FS–240 Consular Report of Birth Abroad, or successor form, to the list of acceptable documents under the "list C" column of Form I–9, Employment Verification Eligibility. Since 2011, Form FS–240 has been exclusively issued by DOS as evidence of a U.S. citizen's birth abroad and acquisition of U.S. citizenship at birth, as well as used to replace a lost, stolen, or damaged Form FS–545 Certification of Birth Abroad or Form DS–1350 Certification of Report of Birth. This technical change will formally recognize the Form FS–240, or successor form, as an acceptable document to establish employment authorization for Form I–9 purposes.

V. Statutory and Regulatory Requirements

A. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The value equivalent of $100 million in 1995 adjusted for inflation to 2015 levels by the Consumer Price Index for All Urban Consumers (CPI–U) is $155 million.

This rule does not exceed the $100 million expenditure in any one year when adjusted for inflation ($155 million in 2015 dollars), and this rulemaking does not contain such a mandate. The requirements of Title II of the Act, therefore, do not apply, and DHS has not prepared a statement under the Act.

B. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States companies to compete with foreign-based companies in domestic and export markets.

C. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

1. Summary

The proposed rule is intended to add new regulatory provisions guiding the use of parole with respect to individual foreign entrepreneurs of start-up entities whose entry into the United States would provide a significant public benefit through the substantial and demonstrated potential for rapid growth and job creation. Such potential would be indicated by, among other things, the receipt of significant capital financing from U.S. investors with established records of successful investments, or obtaining significant awards or grants from certain Federal, State or local government entities. The regulatory amendments would provide the general criteria for considering requests for parole submitted by such entrepreneurs.

DHS assesses that the rule, if finalized, will reduce a barrier to entry for new innovative research and entrepreneurial activity in the U.S. economy. The full potential of foreign entrepreneurs to benefit the U.S. economy is presently limited since many foreign entrepreneurs who seek to enter the United States and manage their own start-up entities do not qualify under existing nonimmigrant and immigrant classifications.[52] If this rule were finalized, some new innovative entrepreneurs will be able to pursue their entrepreneurial endeavors in the United States and contribute to the U.S. economy. In the absence of the rule, these innovative entrepreneurs might be delayed or discouraged altogether in bringing innovation and job creation to the United States.

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[51] The CPI–U produces monthly data on changes in the prices paid by urban consumers for a representative basket of goods and services. *See http://www.bls.gov/cpi/.*

Based on review of data on startup entities, foreign ownership trends, and Federal research grants, DHS expects that approximately 2,940 entrepreneurs, sourced to 2,105 new firms with investment capital and about 835 new firms with Federal research grants could be eligible for this parole program annually. This estimate assumes that each new firm is started by one person despite the possibility of up to three owners being associated with each startup. DHS has not estimated the potential for increased demand for parole among foreign nationals who may obtain substantial investment from U.S. investors and otherwise qualify for entrepreneur parole, because changes in the global market for entrepreneurs, or other exogenous factors, could affect the eligible population. Therefore, these volume projections should be interpreted as a reasonable estimate of the eligible population based on past conditions extrapolated forward. Eligible foreign nationals who wish to apply for parole as an entrepreneur would incur the following costs: A filing fee for the Application for Entrepreneur Parole (Form I–941) in the amount of $1,200 to cover the processing costs for the proposed application; a fee of $85 for biometrics submission; and the opportunity costs of time associated with completing the proposed application and biometrics collection. After monetizing the expected opportunity costs and combining them with the filing fees, an eligible foreign national applying for parole as an entrepreneur would face a total cost of $1,480. Any subsequent renewals of the parole period would result in the same previously discussed costs. Filings to notify USCIS of material changes to the entrepreneur's parole, when required, would result in similar costs; specifically, in certain instances the entrepreneur would be required to submit to USCIS a new form I–941 to notify USCIS of material changes to their parole and would thus bear the direct filing cost and concomitant opportunity cost. However, because the $85 biometrics fee would not be required with such filings, these costs will be slightly lower than those associated with the initial parole request and any request for re-parole.

Dependent spouses and children who seek parole to accompany or join the principal applicant by filing a Form I–131, Application for Travel Document, would be required to submit biographical information and biometrics as well. Based on a principal applicant population of 2,940 entrepreneurs, DHS assumes a total of 3,234 spouses and children would be seeking parole and submitting biometrics. Each dependent would incur a filing fee of $360, a biometric processing fee of $85 (if 14 years of age and over) and the opportunity costs associated with biometrics collection. After monetizing the expected opportunity costs associated with providing biographical information to USCIS and submitting biometrics and combining it with the biometrics processing fee, each dependent applicant would face a total cost of $550. DHS is also proposing to allow the spouse of an entrepreneur paroled under this proposed rule to apply for work authorization. Using a one-to-one mapping of principal filers to spouses, the total population of spouses expected to apply for work authorization is 2,940, which is an upper bound estimate. To obtain work authorization, the entrepreneur's spouse would be required to file Form I–765, Application for Employment Authorization, incurring a $380 filing fee and the opportunity costs of time associated with completing the application. After monetizing the expected opportunity costs and combining it with the filing fees, an eligible spouse would face a total additional cost of $416 (rounded). DHS does not anticipate that this rule, if finalized, would generate significant costs and burdens to private or public entities. While applicants may face a number of costs linked to their business or research endeavors, these costs would be driven by the business and innovative activity that the entrepreneur is engaged in and many other exogenous factors, not the rule itself or any processes related to the rule. Thorough review of academic, business, and policy research does not indicate that significant expected costs or negative consequences linked to drawing in foreign entrepreneurs are likely to occur. As such, DHS expects that the negative consequences, if any, would be greatly exceeded by the positive effects of this rule.

In each case where an entrepreneur would be granted parole under this rule, DHS would have made a determination that parole would yield a significant public benefit and that the person requesting parole merits a favorable exercise of discretion. Consistent with those decisions, the rule would be expected to produce broad economic benefits through the creation of new business ventures that otherwise would not be formed in the United States. These businesses are likely to create significant additional innovation, productivity, and job creation. It is reasonable to conclude that investment and research spending on new firms associated with this proposed rule will directly and indirectly benefit the U.S. economy and create jobs for American workers. In addition, innovation and research and development (R&D) spending are likely to generate new patents and new technologies, further enhancing innovation. Some portion of the foreign entrepreneurs likely to be attracted to this parole process may develop high growth and high impact firms that can be expected to contribute disproportionately to job creation. In summary, DHS anticipates that this proposed rule would produce positive effects that would greatly exceed any negative consequences.

Using an estimate of 2,940 annual applications for significant public benefit entrepreneur parole developed in the ensuing volume projections section of this analysis (these estimates focus only on principal initial filers, not entrepreneurs who might be eligible for a re-parole period of up to three years, or their spouses), DHS anticipates the total cost of this rule for principal filers who face a total per applicant cost of $1,480 to be $4,349.827 (undiscounted) annually for any given year. Dependent spouses and children who must submit Form I–131 and biometrics would face a per-applicant cost of $550, for a total cost of $1,779,604 (undiscounted). Dependent spouses who apply for employment authorization would face a per applicant cost of $416, which DHS projects would total $1,123,630 (undiscounted). Adding together the costs for the principal filers and family members—including filing costs, costs of submitting biometrics, and monetized opportunity costs—yields a total cost of this rule for the first year, 2017 and subsequently 2018, of $7,353,061

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[52] Nina Roberts, *For foreign tech entrepreneurs, getting a visa to work in the US is a struggle,* The Guardian, Sept. 14, 2014, available at *http://www.theguardian.com/business/2014/sep/14/foreign-tech-entrepreneurs-visa-us-struggle;* Amy Grenier, *Majority of U.S. Patents Granted to Foreign Individuals,* April 11, 2014, available at *http://immigrationimpact.com/2014/04/11/majority-of-u-s-patents-granted-to-foreign-individuals/* ("Because of the limitations of the H–1B visa program, and the lack of a dedicated immigrant visa for entrepreneurs or innovators, foreign inventors struggle with inadequate visa options that often prevent them from obtaining permanent residency.")

(undiscounted). The total annual cost of the rule of $7,353,061 can be expected for each subsequent year in the ten-year period. The total ten-year undiscounted cost is $73,530,611.

2. Background and Purpose of the Proposed Rule

As described more fully in preceding sections of the preamble, Section 212(d)(5) of the Immigration and Nationality Act (INA), 8 U.S.C. 1182(d)(5), grants the Secretary of Homeland Security the discretionary authority to parole individuals into the United States, on a case-by-case basis, for urgent humanitarian reasons or significant public benefit. DHS proposes to amend its regulations implementing this authority to increase and enhance entrepreneurship, research and development and other forms of innovation, and job creation in the United States. The proposed rule would establish general criteria for the use of parole with respect to individual entrepreneurs of start-up entities whose entry into the United States would provide a significant public benefit through the substantial and demonstrated potential for rapid growth and job creation.

The purpose of the proposed rule is to attract talented entrepreneurs to the United States who might otherwise choose to pursue such innovative activities abroad, or otherwise be significantly delayed, given the barriers they presently face. In addition to the intangible benefits associated with entrepreneurial innovation, and more tangible but difficult to measure benefits associated with new products, business networks, and possible production efficiencies that such activities are likely to generate, entrepreneurs have been and remain vital to economic growth and job creation in the United States and have generated a cohort of high-growth firms that have driven a highly disproportionate share of net new job creation.[53]

A body of research documents both the importance of entrepreneurial activity to the U.S. economy and its link to immigration. In this background section, DHS does not attempt to comprehensively summarize this large body of work but instead focuses on specific aspects central to the purpose of the rule and to its potential impacts.[54] In summary, DHS focuses on the role of new entrepreneurial firms in job creation in the United States, and the role that immigrant entrepreneurs have played in innovation and the high technology sector.

The labor market of the United States is highly dynamic. DHS analysis of data published by the U.S. Department of Labor's Bureau of Labor Statistics (BLS) indicates that between 2004 and 2013, on average about 847,000 firms were "born" each year and 784,000 "died."[55] To illustrate the extent of the labor market churn, since 1980 the private sector has generated about 16.3 million gross jobs annually but an average of only about 1.4 million net jobs annually. In both general business cycle expansions and contractions, large numbers of jobs are created and destroyed, comprising a key dynamic in the forces of creative destruction.[56] Research into the highly dynamic and volatile labor market in the United States has evolved. Earlier focuses on small- and new-firm size as the primary co-determinants of job creation has been reoriented to focus on the role of a relatively small subset of entrepreneurial firms.

This proposed rule focuses on identifying entrepreneurs associated with types of entrepreneurial firms that are more likely to experience high growth, contribute to innovation in the United States, and create jobs in the country. This narrowed focus is critical to ensuring that parole in individual cases is justified by significant public benefit. Research has shown that the average start-up company does not survive long.[57] Most new firms do not add much net job creation either, as they are not focused on achieving high growth. By some estimates, the vast majority—as much as 95 percent—of all new firms are not substantial job creators or innovators.[58] About 95 percent of new firms start-up with fewer than 20 employees, and about the same percentage ultimately close with fewer than 20 employees, indicating that business turnover is heavily influenced by small firms.[59]

There is significant research, however, demonstrating that a small subset of new firms tends to be highly dynamic and to contribute disproportionately to net job creation. The BLS has highlighted the role of the small subset of high-growth firms that comprise about 2 percent of all firms but have accounted for 35 percent of gross job gains in recent years. "High-growth firms" are defined by the BLS and the Organization for Economic Cooperation (OECD) as those with at least ten employees that grow by at least 20 percent for each of 3 consecutive years based on employment. As of 2012, there were 96,900 high-growth firms in the United States that had created about 4.2 million jobs.[60] A key finding by the BLS is that as high-growth firms age, although they contribute, on average, less and less each year to new jobs, by the time they reach the age of 10 years or more, their size at that point means that the jobs they do add still account for a large share of new jobs. Job creation in the United States for the last several decades has been driven primarily by high-growth firms that tend to be young and new, and by a smaller number of surviving high-growth firms that age for a decade or more.[61]

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[53] *See* Richard L. Clayton, Akbar Sadeghi, David M. Talan, and James R. Spletzer, "*High-employment-growth firms: defining and counting them,*" Office of Industry Employment Statistics, Bureau of Labor Statistics (BLS), Monthly Labor Review (June 2013), p. 1–2, available at: *http://www.bls.gov/opub/mlr/2013/article/pdf/clayton.pdf.*

[54] DHS notes that the body of research concerning immigration in general and its impact on the labor market, most notably germane to earnings and employment of domestic workers, is not addressed in the present analysis.

[55] Figures were obtained from the BLS, Business employment Dynamics, Table 8, "Private sector establishment births and deaths, seasonally adjusted:" Available at *http://www.bls.gov/news.release/cewbd.t08.htm.* Firm "births" in these data only include new firms and thus exclude new franchises and expansions of existing firms.

[56] *See* Ryan Decker, John Haltiwanger, Ron Jarmin, and Javier Miranda, "*The Role of Entrepreneurship in US Job Creation and Economic Dynamism,*" Journal of Economic Perspectives—Vol. 28, Number 3 (Summer 2014), pp. 3–24, available at: *http://pubs.aeaweb.org/doi/pdfplus/10.1257/jep.28.3.3.*

[57] According to BLS findings, "20 percent of newly created establishments don't survive their first year in business, 32 percent don't survive their first two years, and 50 percent don't survive their first 5 years." *See* Richard L. Clayton, Akbar Sadeghi, David M. Talan, and James R. Spletzer,"*High-employment-growth firms: defining and counting them,*" Office of Industry Employment Statistics, Bureau of Labor Statistics (BLS), Monthly Labor Review (June 2013), p. 1, available at: *http://www.bls.gov/opub/mlr/2013/article/pdf/clayton.pdf.*

[58] *See* Jason Wiens and Chris Jackson, "*The Importance of Young Firms for Economic Growth,*" Ewing Marion Kauffman Foundation (2014), pp. 1–2, available at: *http://www.kauffman.org/~/media/kauffman_org/resources/2014/entrepreneurship%20policy%20digest/september%202014/entrepreneurship_policy_digest_september2014.pdf.* See also Hurst, Erik, and Benjamin Wild Pugsley. 2011. "*What Do Small Businesses Do?*" Brookings Paper on Economic Activity, no. 2 (2011), pp. 73–142.

[59] *See* Headd, Brian, "*An Analysis of Small Business and Jobs,*" SBA Office of Advocacy, (2010), p. 6, available at: *https://www.sba.gov/sites/default/files/files/an%20analysis%20of%20small%20business%20and%20jobs(1).pdf.*

[60] *See* R. Clayton et al., (June 2013), supra at N. 46, p. 2–4. For a description of the methodology utilized to measure high growth firms, see OECD, "*OECD-Eurostat Manual on Business Demography Statistics*" (2007), pp. 59–65, available at: *http://www.oecd.org/std/39974460.pdf.*

[61] For specific detailed information on survival rates and employment creation at various intervals along the HGF life span, *see* R. Decker et al., (2014), *supra* at N. 45, pp. 6–24. The BLS and others use

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This highly disproportionate, "up or out" dynamism of high-growth firms has been substantiated by many researchers. The SBA reported that about 350,000 "high impact firms"—defined as enterprises whose sales have at least doubled over a 4-year period and which have an employment growth quantifier of 2 or more over the same period—generated almost all net new jobs in the United States between 1994 and 2006.[62] The Kauffman Foundation, a leading institute on research, data collection, and advocacy for entrepreneurial activity, reports that the top-performing one percent of firms generates roughly 40 percent of new job creation, and, the fastest of them all—the "gazelles"—comprising less than one percent of all companies, generated roughly ten percent of new jobs.[63] The same general result has been found internationally; the OECD reports that between three percent and six percent of all firms can be considered high-growth firms but about one percent can be considered the even more impressive performing "gazelles." [64]

Despite the finding across a large number of studies that small new firms tend to exhibit an "up or out" dynamic in which a small number survive to age five to become high-growth firms or "gazelles," other key findings that have emerged in the literature suggest that the growth and performance (as indicated by metrics that include labor productivity, profitability, revenue, and research and development intensity) of new firms, even high-growth firms, vary substantially.[65] Models that can sort out various business characteristics and economic conditions to predict high-growth probabilities are still in nascent stages. Nevertheless, this proposed rule includes threshold criteria for parole consideration meant to identify entrepreneurs associated with the kinds of promising start-up entities that appear more likely to contribute to American innovation, economic development, and job creation. As described in more detail below, businesses started and run by immigrants have propelled these kinds of broadly shared economic benefits for many years.

Broadly speaking, entrepreneurs engage in research and development (R&D) in order to develop and commercialize new products and technologies. Several studies have found that entrepreneurs tend to engage in R&D spending in the first year, tend to attract patents and other forms of intellectual capital, and tend to attract venture capital financing.[66]

Immigrants have been central contributors to business ownership and entrepreneurship in the United States and abroad. According to OECD data, self-employment rates for immigrants are higher than those of the native-born populations in many counties, including in the United States.[67] Based on the most recent data available from the U.S. Census Bureau, 12.9 percent of the United States population was foreign-born. Their rate of self-employment is about 30 percent higher than that of the native-born population (7.7 percent vs. 5.9 percent; n=1.8 million). The Census Bureau's 2012 Survey of Business Owners showed that 14.4 percent of U.S. firms were owned by at least one person not born a citizen of the United States.[68] In sampling-based studies, the SBA found a higher foreign-born ownership rate, at 16 percent, as did the German-based IZA Institute for the Study of Labor, which put the rate at 18.2 percent.[69]

Many high-growth firms are involved in activities classified in the STEM (science, technology, engineering, and math) fields. The high concentration of immigrant entrepreneurs in these industries has gained much attention. Between 2006 and 2012, one-third of companies financed with venture capital that made an initial public offering had an immigrant founder, a sharp rise from seven percent in 1980. These companies have generated 66,000 jobs and $17 billion in sales.[70] A survey of entrepreneurs in technology-oriented privately held companies with venture backing also showed about one-third were foreign born, and 61 percent held at least one patent.[71]

Further evidence points to similar findings. Between 1995 and 2005, 25 percent of science and technology focused businesses founded in the United States had a foreign-born chief executive or lead technologist. In 2005, those companies generated $52 billion in sales revenue and employed 450,000 workers. In Silicon Valley, the share of immigrant-founded start-ups increased to 52 percent by 2005. In 2006, foreign nationals residing in the United States were involved (as inventors or co-inventors) in about 26 percent of patent applications filed that year. Immigrant founders of Silicon Valley firms tend to be highly educated, with 96 percent holding bachelor's degrees and 74 percent holding advanced degrees, and with 3-quarters of the latter in STEM fields. As of 2010, more than 40 percent of the Fortune 500 companies had been

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the term "gazelles" to differentiate the fastest growing young HGFs.

[62] *See* Spencer Tracy, Jr., "*Accelerating Job Creation in America: The Promise of High-Impact Companies,*" SBA Office of Advocacy (2011), pp. 1–4, available at: *https://www.sba.gov/sites/default/files/advocacy/HighImpactReport.pdf. See also* Acs, Zoltan, William Parsons, and Spencer L. Tracy, Jr., "*High-Impact Firms: Gazelles Revisited.*" Study prepared for the SBA, Office of Advocacy (2008), p. 1, available at*: http://www.sba.gov/advo/research/rs328tot.pdf.* The SBA high-impact cohort is about 6.3% of all firms, which is higher than the 2% high-growth category found in the BLS studies. The SBA cohort is larger because the criteria are slightly less restrictive and it includes older firms.

[63] *See* Dane Stangler, "High-Growth Firms and the Future of the American Economy," *Kauffman Foundation Research Series: Firm Formation and Economic Growth* (2010), p. 2, available at: *http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2010/04/highgrowthfirmsstudy.pdf.*

[64] David B. Audretsch, "*Determinants of High-Growth Entrepreneurship,*" report prepared for the OECD/DBA International Workshop on—High-growth firms: local policies and local determinants, OECD, p. 2–5, available at: *http://www.oecd.org/cfe/leed/Audretsch_determinants%20of%20high-growth%20firms.pdf.*

[65] *See* R. Decker et al. (2014), *supra* at N. 45, pp. 5–7. See also Davis, Steven J., R. Jason Faberman, John Haltiwanger, Ron Jarmin, and Javier Miranda, "*Business Volatility, Job Destruction, and Unemployment.*" American Economic Journal: Macroeconomics 2(2) (2010): 259–87. Research and development intensity is typically measured as the ratio of research and development spending to revenue, net income, or overall costs.

[66] *See* Shah, Sonali K. and Winston Smith, Sheryl and Reedy, E. J., "*Who are User Entrepreneurs? Findings on Innovation, Founder Characteristics, and Firm Characteristics,*" The Kauffman Firm Survey (February 2012), pp. 2–5, available at: *http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2012/02/whoareuserentrepreneurs.pdf.*

[67] OECD, "*Migrant Entrepreneurship in OECD Countries,*" prepared by Maria Vincenza Desiderio (OECD) and Josep Mestres-Domènech for the Working Party on Migration (2011), pp. 141–144, available at: *http://www.oecd.org/els/mig/Part%20II_Entrepreneurs_engl.pdf.* This, and many other similar studies and analyses are based on self-employment rates, which are a proxy, but not perfect measure, of business ownership, because some ownership structures such as partnerships, that could involve a foreign-born owner, are generally not considered to be proprietary.

[68] The categorization of "foreign-born" does not differentiate between lawful permanent residents and naturalized citizens. It also does not provide details of the firm history, implying that some firms owned by persons not born in the United States could have been founded by U.S. citizens and sold to foreign-born persons.

[69] *See* David M. Hart, Zoltan J. Acs, and Spencer L. Tracy, Jr., "*High-tech Immigrant Entrepreneurship in the United States.'* Report developed under a contract with the Small Business Administration, Office of Advocacy (2009), page 8, available at: *https://www.sba.gov/sites/default/files/advocacy/rs349tot_0.pdf.* See also Robert W. Fairlie and Magnus Lofstrom, "*Immigration and Entrepreneurship,*" Institute for the Study of Labor (2013), p. 1, available at: *http://ftp.iza.org/dp7669.pdf.*

[70] This information is found from various sources and found in Stuart Anderson, "*American Made 2.0. How Immigrant Entrepreneurs Continue to Contribute to the United States Economy,*" National Foundation for American Policy, sponsored by the National Venture Capital Association (NVCA) (2013), pp. 3–7.

[71] *Id.* at pp. 2–5.

founded by an immigrant or the child of an immigrant.[72]

To reiterate, high-growth firms tend to be new and young, and one of their primary contributions to the highly dynamic labor market of the United States has been through job creation. High-growth firms tend to innovate and focus on developing new products and services. While no evidence points to immigrant entrepreneurs outperforming native-born entrepreneurs, the relatively intense involvement of immigrant entrepreneurs in successful technology-driven activities suggests substantial economic contributions. While measuring the precise value and impact of innovation is difficult and still at a nascent stage in research, many economists believe innovation creates positive externalities and spillover effects that further drive economic growth.[73]

Notwithstanding the research on the positive effects of high-growth entrepreneurship, there is some evidence of a long-term slowing in start-up dynamism and entrepreneurial activity in the United States; this trend began well over a decade ago, compelling many economists to advocate for policies that attract more entrepreneurs in general.[74] Many business entrepreneurial advocacy centers have also advocated in recent years for the United States to enact a formalized pathway for immigrant entrepreneurs. DHS is aware of one estimate of the potential benefits of a theoretical start-up visa. A Kauffman Foundation study (2013) estimated that, under certain conditions, a start-up visa could create between 500,000 and 1.6 million new jobs after ten years.[75] The potential benefits of attracting immigrant entrepreneurs have not gone unnoticed internationally, as discussed earlier in the preamble. Thirteen of the thirty-four nations who are part of the Organization of Economic Cooperation and Development (OECD) have enacted special immigration programs for entrepreneurs, although the eligibility criteria vary among them to a significant extent.[76]

3. Population of Entrepreneurs Potentially Eligible

DHS cannot precisely predict the volume of new businesses that would start in the United States due to this rule. DHS has instead examined available data to provide an estimate of the population of individual entrepreneurs who may be eligible to request parole consideration under this proposed rule. Given limits on DHS's information about such entrepreneurs, DHS does not know how many people within the estimated eligible population would actually seek such consideration; as such, the estimates contained in this section represent an upper bound to the size of the eligible population. DHS estimated the population of entrepreneurs potentially eligible for parole under this rule based on two sub-groups: (1) Foreign individuals who seek to come to the United States to start a new business with financial backing from a qualified U.S. investor; and (2) foreign individuals who seek to come to the United States to start a new business as recipients of U.S. funded and awarded research grants and who intend to conduct the concomitant research in the United States. DHS assumes that each member of the eligible population will start a business and proposes that the general criterion for investment from a qualified investor (*e.g.* venture capital firms, angel investors, accelerators/incubators) be set at $345,000, while for government grants or awards the general criterion would be $100,000. Based on these amounts, DHS analyzed various past endeavors for the potential sources of funds. DHS estimates that approximately 2,940 foreign nationals annually could be eligible to apply for parole under this proposed rule. Table 1 summarizes the analysis by source of funds.

TABLE 1—NUMBER OF ENTREPRENEURS POTENTIALLY ELIGIBLE

Sub-group	Annual eligibility
New foreign-owned firms funded with investment capital	2,105
New firms funded with U.S. grants or awards that could potentially decide to locate to the United States	835
Total	2,940

DHS has no way of predicting with certainty the actual number of foreign nationals who would seek parole under this proposed rule over time, as the size of the eligible population could change significantly. DHS acknowledges that the estimate of individuals applying annually is an approximation based on past foreign ownership and start-up capital amounts. The analysis utilized to estimate the potential eligible population is also based implicitly on assumptions that: (1) The rule, if finalized, will not significantly change the frequency of U.S. funded grant applications from foreign researchers; and (2) that the rule, if finalized, will not significantly affect the market for foreign entrepreneurs and the market for the types of investment structures the rule will involve. Based on these assumptions and the data limitations, DHS projects that for the first full year that the rule would be effective, and for the second year, annual eligibility will be approximately 2,940.[77] The next section provides key data and analytical approaches utilized to arrive at the population estimates. DHS first considers volume estimates based on official U.S. data. The resulting estimates based on official data are those utilized for the cost projections of the proposed rule. Due to particular constraints in the data, DHS follows with an alternative method of volume estimation that adds robustness to the official estimate.

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[72] Vivek Wadhwa, "*Foreign-Born Entrepreneurs: An Underestimated American Resource,*" Ewing Marion Kauffman Foundation (2008), pp. 2–6, available at: *http://www.kauffman.org/~/media/kauffman_org/z_archive/article/2008/11/wadhwatbook09.pdf.*

[73] See "*SMEs, Entrepreneurship and Innovation,*" OECD (2010), pp 26–28, available at: *http://www.oecd.org/berlin/45493007.pdf.*

[74] *See* R. Decker *et al,* (2014), supra at N. 45, p. 16–22.

[75] *See* Dane Stangler and Jared Konczal, "*Give Me Your Entrepreneurs, Your Innovators; Estimating the Employment Impact of a Startup Visa,*" Ewing Marion Kauffman Foundation, (February 2013), pp. 1–3, available at: *http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2013/02/startup_visa_impact_finalsada.* The estimates are based on a fixed pool of 75,000 startup visas for a 10-year period, in which firm deaths each year cycle some of visa to new entrants.

[76] Most programs have been enacted after 2010. A country list and some descriptive data can be found at Jean-Christophe Dumont, "*Investor Visas in OECD Countries,*" OECD Conference on Global High-Skilled Immigration Policy The national Academies—Board on science, technology and economic policy (2014), available at: *http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_152202.pdf.*

[77] DHS emphasizes that the total is a broad estimate, as the Department has no means to determine the demand for entrepreneurial parole, changes in the eligible population that the rule may cause, time-variant possibilities, and application preferences. These conditions could change, if, for example, some foreign researchers see parole as attractive and apply for federally funded grants that they otherwise might not have in the absence of the rule. In addition, volume estimates should be interpreted to apply to only initial applications, not considerations for re-parole at some future point in time. Lastly, the market for the types of investments involved, such as venture capital, are fluid and becoming more global in scope. DHS has no means to determine how the evolution of these investment markets will affect, or be affected by the proposed rule.

Volume Projections Data and Methodology

A. Grants

Because U.S.-funded research grants may be a qualifying investment under this rule, DHS obtained publicly available data on federally funded grants for fiscal years 2013–2015.[78] Although numerous agencies within the Federal Government award grants to foreign-born individuals, most are humanitarian or development focused.[79] For this reason DHS parsed the very large data set comprising 1.7 million records to obtain a viable analytical cohort. First, the records were filtered to capture Federal Government agencies that award grants to both United States *and* foreign-born recipients. Secondly, the records were sorted to only include the Federal Government agencies that award grants focused on "projects," thereby excluding block and assistance grants.[80] The foreign-born cohort used for the eligibility projections excluded grants made to recipients in U.S. territories, as such recipients may be subject to special considerations outside the parole parameters.[81] DHS also excluded grant amounts recorded as negative, zero, and trivial amounts of less than $1,000—such values were recorded if grants were rescinded or for some other reason not ultimately funded. On average, 138,447 grants comprised the annual resulting analytical cohort derived from the above filtering procedures. Of that total, a small portion, 2,043 grants, or 1.5 percent, were awarded to foreign-born individuals. Having determined a reasonable eligibility threshold of $100,000, DHS proceeded to the next step, to determine the potential annual eligible population of grant-sourced researchers. Over the period of analysis, 41 percent of the Federal grants awarded to foreign recipients equaled or surpassed the $100,000 benchmark, for an average of 835 annually.

B. Investment Capital

To estimate the number of potential new entrepreneurial start-ups, DHS obtained and analyzed data from the BLS and the Census Bureau. From the BLS Business Employment Dynamics (BED) data suite, DHS obtained the number of private establishments aged 1 year or less for nine broad sectors likely to be involved in innovative activity, in order to focus on entrants.[82] Although a reasonable proxy, the number of establishments aged 1 year or less is not a perfect measure of firm start-ups (births). The chosen metric may overstate births, by including expansions and new franchises of existing businesses. Conversely, it may understate the actual number of start-ups, because some fraction of firms does not survive the first year (the data are tabulated in March of the respective year such that the establishments aged 1 year and less are those that opened within the previous year but remained in business as of March of the following year), and those that opened in the previous year and were still in business but had not reached 2 years of age. DHS utilized the relevant figure for March 2015, because the latter is the most recent figure reported in the BED dataset.

For each sector, DHS obtained the corresponding share of firms owned by a person "born a citizen of the United States" from the Census Bureau's Survey of Business Owners data set.[83] [84] For brevity, we utilize the term "foreign" here to describe such firms. The foreign share was obtained by dividing the number of foreign-owned private firms in a sector by the total number of reporting firms in the same sector. This share applies to firms that have a least one owner who was not born in the United States but does not differentiate between various types of ownership structures. The figure for new firms obtained from the BLS BED data was multiplied first by the foreign share to generate an estimate of firms per sector started by a person not born in the United States.

Next, DHS attempted to calculate how many of the firms were started with at least $345,000, the minimum investment threshold that the rule proposes. The SBO data provides ranges of such startup capital amounts but DHS could not conduct a precise estimate because the data does not provide a category bound by the threshold minimum. In fact, the encompassing tranche is very large, from $249,500 to $1 million in range. The SBO does not provide actual cohort data or other information from which DHS could evaluate the distribution and, therefore, DHS has no way of ascertaining how many firms in this large range would occupy the $345,000 to $1 million

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[78] The data were obtained from USASpending.gov: *https://www.usaspending.gov/Pages/Default.aspx.* From the homepage, the data can be accessed from the linked "data download" section. The files were obtained on April 20, 2015.

[79] It is certainly the case that U.S. State governments and other governmental entities issue research grants that foreign recipients could potentially utilize for parole eligibility. However, DHS is not aware of any database that collects and provides such data publicly.

[80] The Federal entities that awarded scientific focused research to foreign recipients were: Agricultural Resource Service, National Institute of Health, Center for Disease Control, Food and Drug Administration, Department of Defense, National Aeronautics and Space Administration, National Oceanic and Atmospheric Administration, National Institute of Standards and Technology, National Science Foundation. The U.S. Department of State and Agency for International Development (USAID) were excluded from the analysis.

[81] There is a particular way in which the data germane to foreign grants were parsed and analyzed. There are two possible foreign indicators listed for each grant. One is the "principal place" involving the research and the other is the "recipient country." The incumbent volume projections are based on the latter because this indicator generally implies that the grant was made to a person or institution outside the United States. The former is not used because this indicator could apply to grants awarded to U.S. or foreign persons in order to conduct the ensuing research outside the United States. Implicit in this analysis is that persons awarded U.S. funded grants that are overseas could conduct their research and innovation in the United States, and are not otherwise precluded from doing so, even if the focus of such research is in a foreign country.

[82] The BLS data is found at *http://www.bls.gov/bdm/bdmage.htm.* DHS utilized the "Establishment age and survival BED data for nation by major industry" set and figures from Table 5, "Number of private sector establishments by age," for the nine major sectors shown in Table 2, above. The BLS does provide figures on firm births that could be used in the present analysis. However, DHS chose establishment age data because it is broken down in a way that corresponds precisely to the innovating sectors, discussed below. The firm birth data is not categorized in the exact same manner. The nine major sectors were chosen to envelope the approximately 430 individual activities that DHS considers to involve "science, technology, engineering, and math" (STEM)." The full list based on the 2012 update can be found at: *http://www.ice.gov/sites/default/files/documents/Document/2014/stem-list.pdf.*

[83] The Census SBO data are found at: *http://www.census.gov/data/tables/2012/econ/sbo/2012-sbo-characteristics.html.* The foreign ownership figures per sector are found under "Characteristics of Business owners," Table SB1200CSBO11: "Statistics for Owners of Respondent Firms by Whether the Owner Was Born in the United States by Gender, Ethnicity, Race, and Veteran Status for the U.S." and the startup capital data are found under Characteristics of Businesses, Table SB1200CSB16: "Statistics for All United States Firms by Total Amount of Capital Used to Start or Acquire the Business by Industry, Gender, Ethnicity, Race, and Veteran Status for the United States: 2007." The foreign ownership share of firms is provided in the table and thus did not need to be calculated by DHS. The SBO data are part of the 2012 survey for which data was released publicly between February and June 2016.

[84] A possible source of upward bias in the foreign ownership share and hence the estimate of eligible entrepreneurs is that this share does not differentiate between foreign owners who came to the United States to open a business and those who acquired one after being in the United States for some period of time (*e.g.,* lawful permanent residents or naturalized citizens). A general finding among a large literature on this topic is that many foreign-born business owners were driven to start a business by "push" factors in the labor market after arrival in the United States. DHS does not have a means to parse out the ownership rate in a more granular way to account for such differences.

segment. As a result, DHS relied on the share of firms in this tranche and the additional tranches over $1,000,000 relative to the share of all firms reporting for the sector, and recognizes that the volume projection is likely larger than is realistic. An additional assumption is that the startup threshold is the same for businesses with native and foreign-born founders. The relevant data and estimates per sector are shown in Table 3.

TABLE 3—SUMMARY OF ENTREPRENEUR ESTIMATES

Sector	New firms	Foreign share (%)	Start-up threshold (%)	Annual eligible
Agriculture	10,182	4.9	2.5	12
Utilities	1,204	10.8	5.5	7
Manufacturing	29,883	11.0	5.4	178
Information	22,855	11.9	2.0	55
Professional Services *	165,425	12.8	1.2	248
Management	7,334	7.3	20.2	108
Waste Services	66,161	16.4	0.9	94
Education	15,226	11.9	0.7	13
Health Care	210,977	18.0	3.7	1,391
Total	....	....	....	2,105

* Abbreviation for "Professional, Scientific, and Technical Services".

C. An Alternative Estimate of Entrepreneurs Based on Investment Structures

DHS recognizes the imperfections in estimating the potential population of eligible entrepreneurs based on extrapolating past conditions of foreign ownership rates and capital thresholds—and specifically, a lack of a demarcation threshold of $345,000—but this approach provides a reasonable approximation of the upper bound of the eligible population in light of the significant data limitations and the uncertainty involved with estimating future entrepreneurial activity. The main benefit of this method is that it is based on official data; a limitation is that it assumes that the annual crop of firms created are entrepreneurial and the types of firms covered by the parole process in the proposed rule. In practice, some, but not all, will be innovators, even though the present analysis focuses on the sectors of the economy linked to STEM activity (DHS is not aware of any methods or data that can allocate a research-innovation share of firms to each sector). Because the volume projections are derived from information obtained from official sources—the BLS and Census Bureau—DHS retains them for purposes of the costs and volume estimates of the proposed rule. However, DHS believes that an alternative method of estimation will inform readers and strengthen the regulatory analysis, by providing a viable comparison to the official projections. In this alternative approach, DHS focuses on the types of investment structures and ventures likely to be involved in the proposed parole process. Specifically, DHS believes that there will be three primary sources of investment for innovative firms (excluding research grants, which are not addressed in this alternative estimate): Venture capital firms, angel investors, and business accelerators and incubators ("incubators" for brevity, henceforth).[85] Hence, by analyzing the foreign component of these structures, data permitting, an alternative estimate of entrepreneurs can be obtained for comparison purposes.

As is the case with the official estimates, this alternative method, which focuses on innovative firms and investment types, also suffers from limitations. Foremost, DHS recognizes uncertainty around utilization rates, *i.e.* how many potential entrepreneurs among the estimated eligible population would actually seek parole under the proposed rule. Second, there is potential overlap in these structures; for example, firms under incubation often receive angel financing and some firms receive both angel financing and venture capital. However, since DHS does not have data to separate out such capital infusions, each of the three investment types is treated as distinct.

For venture capital, DHS consulted the National Venture Capital Association (NVCA) 2016 yearbook. This yearbook provides the number of annual seed venture investments. The data reveal that between 2013 and 2015, an average of 169 first sequence seed investments were made, which DHS considers to be new firms financed with venture capital.[86] To estimate the eligible share of these venture capital backed firms, DHS relied on the finding that about one third of venture financed companies involved a foreign born owner or founder.[87] Based on this share, approximately 56 firms and individuals (assuming each firm would have one foreign individual) annually would be eligible for parole (obtained by multiplying the annual average of 169 seed investments by 0.33). This estimate embodies the assumption that all of the seed venture investments are above the investment threshold.[88]

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[85] DHS is aware that in recent years alternative sources of financing for new and young firms, such as crowdsourcing and merchant cash advances (MCA), to name just two, have become relevant and common in types of industries, and recognizes that such capital could finance the types of foreign established firms that parole under this rule is intended to involve. However, at present, DHS is not aware of sufficient data concerning these new alternative methods to include them in the context of the present analysis.

[86] The NVCA yearbook is found at: *http://nvca.org/research/stats-studies/*. The figures utilized are found in Figure 3.23, "First Sequence by Stage of Development (Number of Deals). "First sequence" venture finance typically describes the round that is in the early stage following the start-up round. It is generally the capital investment round linked to producing and selling the firm's product.

[87] This figure is found in "*American Made 2.0. How Immigrant Entrepreneurs Continue to Contribute to the United States Economy,*" National Foundation for American Policy, sponsored by the National Venture Capital Association (NVCA) (2013), pp. 3–7, available at *http://www.nfap.com/pdf/American%20Made%202.0.Final.pdf*.

[88] Information from the financial services advisory firm Ernst & Young indicates that the median venture capital round for startups is $900,000 based on the average for 2013–2014, and the median seed round is $850,000. Data in a report in Inc. indicates that median venture capital seed round is $1.05 million based on the period 2013–2015. The information can be found at: *http://www.ey.com/Publication/vwLUAssets/Venture_Capital_Insights_4Q14_-_January_2015/$FILE/ey-venture-capital-insights-4Q14.pdf* and at *http://www.inc.com/linkedin/tomasz-tunguz/inflation-deflation-startup-fundraising-market-tomasz-tunguz.html,* in order. Although the terms "seed" and "startup" can be convoluted, generally seed rounds preceded startup finance sequentially. Seed

Continued

To obtain an incubator estimate, DHS obtained publicly available information from SeedDb, which provides data on U.S. incubators collected from industry associations and fee-based data providers, including CB Insights and Crunchbase, which are two of the largest data providers for venture capital, angel investors, and accelerators.[89] The data are not collated in a way amenable to conducting a cohesive firm-by-firm or firm-wide analysis, but a DHS review of the available data indicates that the date range of firms included is about 2006–2016 (as of the last DHS data pull on March 20, 2016). The total number of firms is 6,248, yielding an annual average over 11 years of 568. Since all of these firms had to enter incubation at some point in the 11-year period, 568 is a reasonable estimate of the average number of firms entering incubation per year. One of the data suites lists the total number of companies incubated for each incubator and the countries that the companies were located in. Since there is wide variation in the number of companies per incubator, ranging from 1 to over a thousand, DHS grouped the incubators by country and then weighted each one for its share of total companies. The resulting weighted average indicates that one quarter of incubated companies were foreign.[90] Applying the 25 percent foreign share to the annual 568 firms, DHS estimates that about 144 firms could be eligible annually. DHS expects that not all foreign firms that enter incubation will meet the $345,000 investment threshold, but because DHS will potentially consider other factors for such firms, a threshold rate is not applied to the estimate for purposes of this analysis.

Having estimated 56 venture firms and 144 incubator firms as potentially eligible, DHS next estimated the largest source of startup investment, angel investors. Based on the most recent data from the Center for Venture Research, about 25 percent of angel investments are made at the seed and startup stage. For the 71,000 companies receiving angel financing per year, about 17,750 could be considered new, which compares favorably to other, unrelated sources that note that about 16,000 new firms are financed with angel investments per year.[91]

DHS used the 17,750 annual figure for angel backed startups and multiplied that number by the same 25 percent rate for foreign identifiers found in the SeedDB data. DHS is aware that many angel investments are made at low levels and that there is a wide range of such investment amounts. DHS does not have publicly available data in which to analyze a distribution of angel backed firms, and operates under the assumption that the $345,000 average is also the median, as is the case for a normal distribution. DHS multiplied the resulting foreign cohort by 0.5. The result of these extrapolations yields a figure of 2,151, which is an estimate of the potential population of eligible new firms annually financed by angel investments. By adding the three investment-type estimates together—144 incubator firms, 56 venture-backed firms, and 2,151 angel-backed firms—the resulting sum is 2,351. While uncertainties and limitations of the data involved in the volume estimates have been enunciated in detail, the closeness of this estimate to the 2,105 figure based on the Census and BLS data, adds robustness and confidence to the official estimate utilized in the cost projections.

D. Potential Variability in the Volume Projections

This section discusses several potential cohorts involving entrepreneurial activity that is difficult to estimate.

In light of the potential benefits to the U.S. economy and job creation, DHS is proposing this rule to provide a mechanism that, consistent with the requirements of the INA, encourages foreign entrepreneurs described herein to form and create innovative firms in the United States. In 2011, DHS began outreach and stood up the Entrepreneurs in Residence initiative to try to encourage entrepreneurship among foreign nationals.[92] DHS began tracking the number of foreign nationals who indicated interest in starting up an entrepreneurial endeavor at some point during their admission as an H–1B nonimmigrant. Over the past four fiscal years (FY 2010–2013), an average of 77 foreign nationals have indicated such interest. In light of the relatively small numbers of foreign nationals who indicated their entrepreneurial intentions, DHS believes that considering parole requests under this rule will promote further innovation and other economic benefits in addition to those created by existing programs and policies used by foreign nationals to pursue high-growth entrepreneurial activity in the United States. If the rule is finalized, there could be some small substitution effects as some portion of this cohort could switch to seeking parole instead of relying on other existing nonimmigrant programs and policies. However, DHS does not believe such substitution would occur on a large scale because the ability to be admitted to the United States as a nonimmigrant offers materially more benefits and protection than parole.

In addition, the proposed rule lists a number of ancillary conditions for eligibility—and conversely a number of conditions that would leave individuals unlikely or unable to be paroled into the United States (or continue to be paroled in the country). Because ancillary conditions can be considered for eligibility, the actual volume may be larger than the estimates herein. Two examples are that under the proposed rule, applicants must maintain household income greater than 400 percent of the poverty line and that the qualifying start-up capital cannot come from family members. The volume estimates presented in this analysis assume all ancillary eligibility conditions are met.

Finally, two potential elements of the eligible population are considered. First, as alluded to in the summary, the volume estimates and ensuing cost estimates assume one individual owner for each new firm; under the proposed rule, DHS would allow up to three individuals per firm to seek parole but does not attempt to estimate how many of the startups could have more than one owner. Second, the volume estimate for grants is based on Federal awards only. DHS will consider eligibility based on State or local grants and awards, including those from State or local Economic Development Corporations (EDCs). Although, unlike in the case of Federal awards, there is not a database capturing State and local grants or the transmission mechanisms through which some Federal grants are distributed to other entities, such as EDCs.

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typically "refers" to capital utilized to found the firm and initialize concept and product development while "startup" generally refers to new capital utilized to support initial production and operations.

[89] The SeedDB information is found at the Web site *is://www.seed-db.com/*.

[90] This foreign share found by DHS in the analysis corresponds strongly to a finding in a study of high technology firms that found that 24 percent of such firms were founded by a foreign born person. *See* "America's New Immigrant Entrepreneurs," Vivek Wadhwa, AnnaLee Saxenian, Ben Rissing, and Gary Gereffi, available at: *http://people.ischool.berkeley.edu/~anno/Papers/Americas_new_immigrant_entrepreneurs_I.pdf*.

[91] This figure is reported in, among other sources: *http://www.angelblog.net/Angels_Finance_27_Times_More_Start-ups_Than_VCs.html* and *http://www.entrepreneurship.org/emed/angel-investing-versus-venture-capital-part-i.aspx*.

[92] Source: USCIS Announces "Entrepreneurs in Residence Initiative" available at: *http://www.uscis.gov/news/public-releases-topic/business-immigration/uscis-announces-entrepreneurs-residence-initiative. See also http://www.uscis.gov/eir/visa-guide/entrepreneur-visa-guide*.

4. Costs

A. Principal Filer Costs

The proposed rule would permit certain foreign nationals to apply for a 2-year initial period of parole into the United States provided they meet the proposed eligibility criteria. Those who seek such parole into the United States would face the costs associated with the application, which involve a $1,200 application fee plus other costs, detailed below. The costs would stem from filing fees and the opportunity costs of time associated with filing the Application for Entrepreneur Parole, Form I–941.

The proposed filing fee for Form I–941 is $1,200. The fee is set at a level intended to recover the anticipated processing costs to DHS.[93] In addition, DHS is proposing that applicants for parole as an entrepreneur submit biometrics and incur the $85 biometric services fee. Because entrepreneurs could start firms in any number of occupations, DHS believes it is appropriate to utilize the mean hourly wage for all occupations, which is $22.71.[94] In order to anticipate the full opportunity cost to petitioners, DHS multiplied the average hourly U.S. wage rate by 1.46 to account for the full cost of employee benefits such as paid leave, insurance, and retirement, for a total of $33.16 per hour.

DHS estimates that the proposed application would take 1.33 hours to complete. After DHS receives the application and fees, if the applicant is physically present in the United States, USCIS will send the applicant a notice scheduling him or her to visit a USCIS Application Support Center (ASC) for biometrics collection. Along with the $85 biometric services fee, the applicant would incur the following costs to comply with the proposed biometrics submission requirement: The opportunity cost of traveling to an ASC, the mileage cost of traveling to an ASC, and the opportunity cost of time for submitting his or her biometrics. While travel times and distances vary, DHS estimates that an applicant's average roundtrip distance to an ASC is 50 miles, and that the average time for that trip is 2.5 hours. DHS estimates that an applicant waits an average of 1.17 hours for service and to have his or her biometrics collected at an ASC, adding up to a total biometrics-related time burden of 3.67 hours.[95] By applying the $33.16 hourly time value for applicants to the total biometrics-related time burden, DHS finds that the opportunity cost for a principal applicant to travel to and from an ASC, and to submit biometrics, would total $121.68.[96] In addition to the opportunity cost of providing biometrics, applicants would experience travel costs related to biometrics collection. The cost of such travel would equal $28.75 per trip, based on the 50-mile roundtrip distance to an ASC and the General Services Administration's (GSA) travel rate of $0.575 per mile.[97] DHS assumes that each individual would travel independently to an ASC to submit his or her biometrics, meaning that this rule would impose a time cost on each of these applicants.

DHS estimates that each principal parole applicant would incur the following costs: $1,285 in filing fees to cover the processing costs for the application and biometrics; $194.53 after summing the monetized cost of travel to submit biometrics, the total opportunity costs of time of the initial applications, biometrics, and estimated travel costs, resulting in a total cost of $1,479.53 per application, rounded to $1,480.[98] If DHS receives 2,940 applications from persons eligible to apply, DHS anticipates that such applications would result in annual filing fee transfers of $3,777,900 (undiscounted), which comprise the application fee and cost of submitting biometrics, and opportunity and other burden costs of $571,927, for a total annual cost of $4,349,827. Any subsequent renewal of the parole period or material changes requiring the filing of an amended application would result in costs similar to those previously discussed, with the possible exception of travel costs, since the applicant would not be required to depart the United States and re-enter.

B. Dependent Spouses and Children

The proposed rule would require all dependent family members (spouses and children) accompanying or joining the entrepreneur to file a Form I–131, Application for Travel Document, and would require all spouses and children 14 years of age through age 79 to submit biometrics. Those spouses and children would face the costs associated with filing the application and submitting biometrics.

DHS recognizes that many dependent spouses and children do not currently participate in the U.S. labor market, and as a result, are not represented in national average wage calculations. In order to provide a reasonable proxy of time valuation, DHS has to assume some value of time above zero and therefore uses an hourly cost burdened minimum wage rate of $10.59 to estimate the opportunity cost of time for dependent spouses. The value of $10.59 per hour represents the Federal minimum wage with an upward adjustment for benefits.[99] The value of $10.59 per hour is consistent with other DHS rulemakings when estimating time burden costs for those who are not authorized to work.[100]

DHS would require dependents of parole applicants (spouses and children of the parole applicant) to file an Application for Travel Document (Form I–131) in order to be scheduled for biometric submission. There is a $360 filing fee associated with Form I–131, and DHS estimates it will take 3.56 hours to complete each submission. In addition to filing the Form I–131, each dependent spouse and child 14 years of age and over would be required to submit biometric information (fingerprints, photograph, and signature) by attending a biometrics services appointment at a designated USCIS Application Support Center (ASC). The biometrics processing fee is $85.00 per applicant. In addition to the $85 biometrics services fee, the applicant would incur the following costs to comply with the biometrics submission requirement: The opportunity and mileage costs of traveling to an ASC, and the opportunity cost of submitting his or her biometrics. While travel times and distances vary, DHS estimates that an applicant's average roundtrip distance to an ASC is 50 miles, and that the average time for that trip is 2.5 hours.[101] DHS estimates that an applicant waits an average of 1.17 hours for service and to have his or her biometrics collected at an ASC, adding up to a total biometrics-related time burden of 3.67 hours. In addition to the opportunity cost of providing biometrics, applicants would experience travel costs related to biometrics collection. The cost of such travel would equal $28.75 per trip, based on the 50-mile roundtrip distance to an ASC and the General Services Administration's (GSA) travel rate of $0.575 per mile.[102] DHS has assumed that each applicant would travel independently to an ASC to submit his or her biometrics, meaning that this rule would impose a time cost on each of these applicants. DHS also assumed all children were over the age of 14 for the purposes of this analysis and, therefore, this cost estimate may be slightly overestimated.

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[93] USCIS calculates its fees to recover the full cost of USCIS operations, including meeting national security, customer service, and adjudicative processing goals. As with other fees, USCIS uses Activity Based Costing (ABC) to assign costs to specific benefit requests. This model uses completion rates (actual or estimated depending on whether the benefit type is already being adjudicated) to calculate a proposed fee or fee adjustment for a benefit type. A completion rate reflects an average time an adjudicator spends actually working on a case but does not include "queue" or wait times. Because parole under this proposed rule has not yet been implemented, the completion rate used is based on a 4-hour estimate provided by USCIS' subject matter experts. At this time, USCIS has estimated that 30 additional staff would be required to satisfy the forecasted workload associated with this rule. However, USCIS requires adjudicators to report actual adjudication hours and case completions by benefit type. This reporting will occur after this rule is implemented. Adjudication hours will be divided by the number of completions for the same time period to determine the *actual* average completion rate. This rate will be used in future fee adjustments and will help determine future staffing allocations necessary to handle the projected workload for parole under this proposed rule.

[94] *See* National Occupational Employment and Wage Estimates United States. May 2014. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics program. Available at *http://www.bls.gov/oes/2014/may/oes_nat.htm.*

[95] Foreign nationals who submit their applications from outside the United States would still be required to pay the $85 biometric processing fee and travel to a USCIS office abroad, if available, or a U.S. embassy or consulate office for biometric processing. Due to data limitations, and to capture general impacts of the rule, DHS has estimated costs of submitting biometrics under the assumption that all applicants are traveling to an ASC in the United States.

[96] Calculation: $33.16 * 3.67 hours = $121.68.

[97] Calculation: 50 miles multiplied by $0.575 per mile equals $28.75. *See* 79 FR 78437 (Dec. 30, 2014) for GSA mileage rate.

[98] Calculation: $1,285 + 194; $1,285 is the sum of the direct cost of the $1,200 filing fee and the $85 cost of biometrics. The $194 (rounded) figure is obtained by adding the cost of travel ($28.75) plus the total opportunity cost of $166, the latter of which is the product of the total time burden (5 hours) and the average burdened hourly wage ($33.16).

[99] U.S. Department of Labor, Wage and Hour Division. The minimum wage in effect as of July 24, 2009. Available at *http://www.dol.gov/dol/topic/wages/minimumwage.htm.* The calculation for total employer costs for employee compensation for dependent spouses and children of principals with an approved Form I–140: $7.25 per hour × 1.46 = $10.59 per hour.

[100] *See* "Employment Authorization for Certain H–4 Dependent Spouses; Final rule," 80 FR 10284 (25 Feb. 2015); and "Provisional and Unlawful Presence Waivers of Inadmissibility for Certain Immediate Relatives; Final Rule," 78 FR 536, 572 (3 Jan. 2013).

DHS projects that approximately 3,234 dependents would be required to file a Form I–131 and submit biometrics, based on the estimate of 2,940 principal applicants and using a multiplier for expected family members of 1.1.[103] The total cost for those spouses and children requesting parole under this program includes the filing fee, biometrics processing fee, travel costs associated with biometrics processing, and the opportunity cost of filing the Form I–131 and submitting biometrics. The total time burden is 7.23 hours. At the cost-burdened wage, the total opportunity cost is $76.53. Adding the $28.75 cost of travel, the total non-filing cost is estimated to be $105.78, and the total cost per applicant is $550. At the projection of 3,234 applicants, the non-filing cost is $340,474 (undiscounted), and combined with filing costs of $1,439,130, the total estimated cost for dependents germane to Form I–131 is $1,779,604.

In addition, DHS proposes to allow unrestricted employment authorization for spouses of entrepreneurs granted parole under this rule. DHS proposes to permit these individuals to apply for employment authorization by filing Form I–765. To estimate the number of potential persons applying for employment authorization, DHS used a simple one-to-one mapping of entrepreneurs to spouses to obtain 1,813 spouses, the same number as entrepreneur parolees.

The current filing fee for Form I–765 is $380.00. The fee is set at a level to recover the processing costs to DHS. Based on the projection of 2,940 applicants, the total filing cost is $1,117,200 (undiscounted). DHS estimates the time burden of completing Form I–765 is 3.42 hours.[104] At the cost-burdened wage, the total opportunity cost is $36.20. At the projection of 2,940 applicants, the non-filing cost is $106,430 (undiscounted) and combined with filing costs of $1,117,200, the total estimated cost for spouses germane to Form I–765 is $1,223,630.

In addition to the filing costs, applicants for parole may face other costs associated with their entrepreneurial activities. These could include the administrative costs of starting up a business, applying for grants, obtaining various types of licenses and permits, and pursuing qualified investments. However, these costs apply to the entrepreneurial activity and the business activity that the applicant has chosen to be involved in and are not driven by the parole process or other governmental functions attributable to the rule itself. Hence, DHS does not attempt to estimate, quantify, or monetize such costs.

Lastly, DHS recognizes that some individuals who were lawfully admitted in the United States in certain nonimmigrant classifications may seek parole. They would thus apply for parole and, if approved, exit the United States and request to be paroled into the United States at a port of entry, as parole will not involve any direct change from other nonimmigrant status. Such applicants would bear the travel costs of exit and returning to a port of entry. However, because there are no similar programs for comparison, DHS cannot determine the demand for parole or substitution effects from other classifications and thus cannot estimate, quantify, or monetize such potential travel costs. Finally, because the program allows for re-parole under conditions that DHS has set, entrepreneurs and their spouse and children, if applicable, would likely face filing and opportunity costs associated with applying for re-parole. However, DHS has no means of estimating the share of the potential eligible population that would seek and be eligible for re-parole, hence re-parole conditions are not included in this analysis. In summary, DHS believes that it is possible that there could be some substitution into the proposed parole program from other programs and such applicants and dependents would incur travel and possible other costs related to exit and re-entry.

C. Potential for Negative U.S. Labor Market Impacts

DHS does not expect the rule to generate significant costs or negative consequences. Extensive review of information relevant to immigrant entrepreneurship indicates that while much about the impact of such entrepreneurship is not known, there is no reason to expect that substantial negative consequences, including adverse impact on domestic workers, are likely. The possibility that immigrant entrepreneurs may displace (“crowd-out”) native entrepreneurs has been raised by a few researchers. One study indicated that a very small number of native entrepreneurs were possibly displaced by immigrant entrepreneurs.[105] However, because of difficulties in controlling for a large amount of variables related to entrepreneurship, other researchers have noted that this finding only raises the possibility that displacement could not be ruled out completely, but did not actually provide irrefutable evidence that it had occurred.[106] Another study, conducted by the Brookings Institution, did not find displacement but acknowledged that more research and refined control techniques, along with longitudinal data, would need to be studied before ruling out the possibility completely.[107] In any event, the purpose of the proposed parole rule is to foster innovation and entrepreneurial activities in new or very young endeavors, where the literature much more decisively indicates a strong potential of creating new net jobs for U.S. workers, offsetting any potential negative impacts for this group.

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[101] DHS has estimated travel distances and ensuing travel times at 2.5 hours in prior rulemakings. *See, e.g.,* "Employment Authorization for Certain H–4 Dependent Spouses; Final rule," 80 FR 10284 (25 Feb. 2015); and "Provisional and Unlawful Presence Waivers of Inadmissibility for Certain Immediate Relatives; Final Rule," 78 FR 536, 572 (3 Jan. 2013).

[102] *See* U.S. General Services Administration Web site for Privately Owned Vehicle (POV) Mileage Reimbursement Rates, *http://www.gsa.gov/portal/content/100715* (accessed August 8, 2015).

[103] The multiplier of 1.1 was obtained from DHS estimates of the average historical ratio of principal versus dependent recipients of LPR status. DHS studies based on statistics obtained from office of Immigration Statistics reveal that multipliers for the employment preference categories EB–1, EB–2, and EB–3 range from 2.04 to 2.27. DHS believes that 2.1. is a reasonable multiplier for the estimates and utilized this multiplier in regulatory assessments involved in American Competitiveness in the Twenty-First Century Act, (AC21) provisions, specifically: "Retention of EB–1, EB–2, and EB–3 Immigrant Workers and Program Improvements Affecting High-Skilled Nonimmigrant Workers" (RIN 1615–AC05), proposed rule. Because the Form I–131 filings relevant to this rule do not apply to principals, only spouses and dependent children, DHS believes it is valid to subtract 1 from the 2.1 multiplier to yield the final multiplier of 1.1.

[104] Source: Paperwork Reduction Act (PRA) Supporting Statement for Form I–765 (OMB control number 1615–0040). The PRA Supporting Statement can be found at Question 13 on *Reginfo.gov* at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201502-1615-004*.

DHS recognizes that the potential inclusion of spouses can incur labor market implications and possibly impact U.S. workers. As was noted in previous sections of the regulatory impact analysis, DHS did not attempt to assess or measure the labor market impact of the estimated entrepreneurs potentially eligible for parole because as founders of firms, these persons would not affect the labor market in the same way as other workers. Although spouses could have labor market impacts as new labor market entrants, DHS believes such potential impacts will be negligible. The main reason is that the size of the potential new cohort is very small. As of the end of 2015, there were an estimated 157,130,000 people in the U.S. civilian labor force.[108] Consequently, the estimated “new” available workers in the first year would represent approximately 0.001 percent of the overall U.S. civilian labor force.[109] DHS believes this fraction is too small to have a significant impact on the labor market.

While the figures above apply to the general U.S. labor force, DHS recognizes that concentration of new labor force entrants can impact specific labor markets. DHS believes that any such potential impacts linked to this rule will be insignificant. The NVCA and other sources of information that DHS reviewed indicates that while the area of California known as Silicon Valley has traditionally been, and continues to be, the primary recipient geographically for technology startup capital, other large urban centers on the East Coast and, even more recently, parts of the Mid- and Mountain West have seen increased technology startup activity. To provide just one example of a potential area-specific impact, DHS considered the San Jose-San Francisco-Oakland (CA) Combined Statistical Area (CSA) conjoining the seven Metropolitan Statistical Areas (MSAs) and nine encompassed counties constituting the economic linkages of Silicon Valley. Based on data from the BLS, the population of this CSA is about 8.6 million (as of May 2014) and the employed population (a narrower measure of the labor market than the labor force) about 3.75 million. If the share of new entrants is based on the proportion of venture capital to the area, which is 42 percent, then 2,746 spousal entrants could impact the area.[110] Assuming such entrants gain employment, this cohort represents just 0.02 percent of the employed population of the specific CSA.

D. Government Costs

The INA provides for the collection of fees at a level that will ensure recovery of the full costs of providing services, including administrative costs and services provided without charge to certain applicants and petitioners. *See* INA section 286(m), 8 U.S.C. 1356(m). DHS has established the fee for the adjudication of proposed Form I–941 based on notional application filing volumes and estimated resource commitments. During the biennial fee review, DHS will examine whether the fee is sufficient to recover the full costs of adjudication, as required by the INA.

5. Benefits

As referenced previously, evidence suggests that innovation-focused start-ups contribute disproportionately to job creation. The proposed rule would reduce entry barriers, and thus support efforts by foreign entrepreneurs to generate entrepreneurial activity in the United States.

The proposed rule is expected to generate important net benefits to the United States economy. For one, expenditures on research and development by the estimated annual grant-based researchers that DHS has identified that could qualify for entrepreneur parole would generate direct and indirect jobs. In addition, this research-focused spending could potentially generate patents, intellectual property, licensing, and other intangible assets that can be expected to contribute to innovation and technological advances and spill over into other sectors of the overall economy. DHS acknowledges that it is extremely difficult to gauge the actual economic value of such assets and that peer-reviewed research in this area is still nascent. Despite the nascent stage of the research and the difficulty of measuring quantitatively the benefit of innovation driven by new high technology firms, various research indicates that the innovation driven by entrepreneurs contributes directly to economic growth, generates important efficiencies and cost reductions for firms that utilize such innovation, and increases productivities and profitability for firms that benefit indirectly through new products generated by such innovation.

Lastly, DHS believes that a subset of the start-up firms formed by foreign entrepreneurs during the proposed parole period could eventually become high-growth firms that generate high levels of profitability and contribute disproportionately to job creation in the United States.

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[105] Fairlie, R. W., and B. D. Meyer. “The effect of immigration on native self-employment.” *Journal of Labor Economics* 21:3 (2003): 619–650, available at: *http://people.ucsc.edu/~rfairlie/papers/published/jole%202003%20-%20native%20se.pdf.*

[106] *See* Magnus Lofstrom, “Immigrants and Entrepreneurship,” Public Policy Institute of California, USA, and IZA, Germany (2014), p. 4, available at: *http://wol.iza.org/articles/immigrants-and-entrepreneurship.pdf.*

[107] *See* Zoltan J. Acs and David M. Hart, “Immigration and High-Impact, High-Tech Entrepreneurship,” *Brookings,* Issues in Technological innovation (February 2011), available at *http://www.brookings.edu/research/papers/2011/02/immigration-hart-acs.*

[108] *See* News Release, United States Department of Labor, Bureau of Labor Statistics, Local Area Unemployment Statistics, Regional and State Unemployment—2015 Annual Averages, Table 1 “Employment status of the civilian non-institutional population 16 years of age and over by region, division, and state, 2014–15 annual averages” (Mar. 24, 2016), available at *http://www.bls.gov/news.release/pdf/srgune.pdf.*

[109] Source: United States Department of Labor, Bureau of Labor Statistics, Local Area Unemployment Statistic. Figure applies to seasonally adjusted level for December 2014, available at: *http://data.bls.gov/timeseries/LNS11000000.* Calculation for new worker labor force share: 1813/157,130,000.

[110] The employment figures are provided by the BLS, Occupational Employment Statistics (OES), found at: *http://www.bls.gov/oes/current/oes_42100.htm.* The population data is provided by the Census Bureau, which tabulates CSAs: “Combined Statistical Area Totals Dataset: Population and Estimated Components of Change: April 1, 2010 to July 1, 2014” (CSV), 2014 Population Estimates. United States Census Bureau, Population Division. March 2015. The information on the venture capital share for the region is found in the NVCA 2015 yearbook, and is found in figure 8, p. 14. The calculation is as follows: .(42 × 1813) = 761, which is then divided by the CSA population of 3,750,000.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (Mar. 29, 1996), requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of fewer than 50,000. Individuals are not defined as a "small entity" by the RFA.

DHS has reviewed this regulation in accordance with the Regulatory Flexibility Act and certifies that this rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would provide guidance on the use of parole for entrepreneurs who seek it on a voluntary basis. The proposed rule would not mandate that all individuals apply for parole. This proposed rule provides flexibilities and options that do not currently exist for individuals who wish to establish or operate a start-up business in the United States. Importantly, the proposed rule does not require any individuals or businesses, including those created by foreign nationals, to seek parole—either generally or as a specific condition for establishing or operating a business in the United States. Rather, as mentioned previously, this proposed rule is intended to provide an additional flexibility for foreign individuals who are unable to obtain another appropriate nonimmigrant or immigrant classification, in order to facilitate the applicant's ability to oversee and grow the start-up entity. If any individual believes this rule imposes a significant economic impact, that individual could simply choose to not avail themselves to the requirements of the rule and would then incur no economic impact. As discussed previously, this rule imposes direct filing costs of $1,285 (which includes the $1,200 application fee and the $85 biometrics fee), plus $194 in time-related opportunity costs for those individuals who do choose to apply for entrepreneur parole. This cost is relatively minor when considering the costs of starting up a new business and the capital necessary to start a business.

Under the general term "entrepreneur," DHS includes those who desire to form firms with investment funds from certain U.S. investors. For purposes of the RFA, the regulatory requirements place compliance costs and establish eligibility criteria for the individual requesting consideration for parole under this proposal. DHS believes that the costs of application for parole would burden the individual applicant, and not the entrepreneurial venture (firm). This proposed rule would not alter or change the normal procedure for fundraising or other start-up administrative costs that occur in forming a business entity. Such costs are not direct costs of this rule and could include, but are not limited to, business application fees, legal fees, and licensing that precede significant infusions of investment, the latter of which are primarily utilized for operational and capital expenses in order to produce goods or services.

It is possible that some of the 2,940 estimated entrepreneurs who could be eligible for parole annually could involve business structures in which the filing fees are paid by a business entity. In the event that small business entities are impacted by this proposed rule because they choose to pay the filing fees on behalf of an individual entrepreneur, DHS believes that the filing cost of $1,285 per application would be insignificant compared to such entities' annual gross revenues, potential for revenue, and other economic activity. DHS welcomes public comment on the numbers of small business entities that may be impacted by this rule, the likely compliance costs for these entities, and any potential alternatives that may minimize these compliance costs.

For businesses that may pay the filing costs, the expected impact to such businesses would be small. For businesses that utilize either the minimum threshold of $100,000 from a Federal grant or $345,000 in capital investment to source the filing costs, such costs would constitute 1.3 percent and 0.4 percent, respectively, of the total capital amount. These relatively low cost proportions apply to those firms that only obtain the minimum investment amounts. In addition, DHS analyzed the cost impact relative to more typical RFA indices. DHS analysis of Census Bureau data on the smallest firms found that the average revenue based on sales receipts for firms with no paid employees is $309,000, while the average for firms with one to four paid employees is $411,000.[111] The filing cost relative to these averages is 0.42 percent and 0.31 percent, respectively.

DHS also analyzed the average revenue for new firms. Since the proposed rule defines a new firm as one that is less than three years old, DHS grouped private sector firms for the 2012 survey as those responding that the year of establishment was either 2012, 2011, or 2010. DHS obtained the average revenue per firm and then weighted the average by the yearly proportion of firms. Based on the resulting weighted average of $162,000, such new firms would face a filing-cost burden of 0.8 percent.[112] DHS notes that there is a large difference between the revenue of new firms with paid employees and those without such employees (*i.e.,* sole proprietors). For the latter, average revenues are about $34,000, and the cost burden would be 3.8 percent. However, because a central component of this parole program requires a demonstration of significant public benefit in the form of economic activity and job growth, DHS does not anticipate that sole proprietors would be eligible to participate in this program.

In summary, DHS believes that per-applicant costs would be primarily incurred by the individual (which is not covered by the RFA), any direct cost due to this rule would be relatively minor, and these costs would only be borne by those who voluntarily choose to apply for parole under this rule. While the applicant for parole may be the owner of a firm that could be considered small within the definition of small entities established by 5 U.S.C. 601(6), DHS considers the applicants to be individuals at the point in time they are applying for parole, particularly since it is the individual and not the entity that files the application and it is the individual whose parole must serve a significant public benefit under this proposed rule. Furthermore, even if firms do voluntarily decide to incur the compliance costs on behalf of the individual requesting consideration for parole under the proposed criteria, the only compliance costs those businesses would be permitted to incur would be the filing costs for the applications. As indicated previously, based on the comparison metric used, those costs are expected to be insignificant.

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[111] The data utilized for the analysis are found in the SBO Table SB1200CSA09, "Statistics for All U.S. Firms With Paid Employees by Industry, Gender, and Employment Size of Firm for the U.S. and States: 2012, 2012 Survey of Business Owners: *http://census.gov/library/publications/2012/econ/2012-sbo.html*. The file location is: *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO_2012_00CSA09&prodType=table*. The figures are rounded from $309,279 and $410,900, respectively.

[112] The data utilized for the analysis are found in the SBO Table SB1200CSCB11, "Statistics for All U.S. Firms by Year the Business Was Originally Established or Self-Employment Activity Begun by Industry, Gender, Ethnicity, Race, and Veteran Status for the U.S.: 2012: 2012 Survey of Business Owners: *http://census.gov/library/publications/2012/econ/2012-sbo.html*. The file location is: *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=SBO_2012_00CSCB11&prodType=table*. The average revenue figure is rounded from $162,293.

Based on the evidence presented in this RFA section and throughout this preamble, DHS certifies that this rule would not have a significant economic impact on a substantial number of small entities.

E. Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13, all Departments are required to submit to the Office of Management and Budget (OMB), for review and approval, any reporting requirements inherent in a rule. *See* Public Law 104–13, 109 Stat. 163 (May 22, 1995).

This proposed rule requires that an applicant requesting entrepreneur parole complete an Application for Entrepreneur Parole, Form I–941, and is considered a new information collection that is covered under the PRA. To allow spouses and dependent children of the entrepreneur to remain united as a family, DHS will need to revise the Application for Travel Document, Form I–131, for these dependent family members to request parole.

This proposed rule also requires a revision to Employment Eligibility Verification, Form I–9, which has been previously approved for use by OMB under the PRA. The OMB Control Number for this information collection is 1615–0047. In accordance with new 8 CFR 274a.2(b)(1)(v)(A)(*5*) DHS is revising the Employment Eligibility Verification, Form I–9, Lists of Acceptable Documents, List A item 5 to replace "nonimmigrant alien" with "individual," to replace "alien's nonimmigrant" with "individual," and to add "or parole" after "status" in List A item 5.b.(2) allowing an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole.

Lastly, this proposed rule will require minor revisions to the Application for Employment Authorization, Form I–765, to reflect proposed changes that allow spouses of an entrepreneur parolee to request employment authorization.

DHS has submitted these information collection requests to OMB for review and approval under the PRA. Accordingly, DHS is requesting comments on these impacted information collections. See the **ADDRESSES** section above for instructions on how to submit comments to DHS and OMB on the information collection provisions of this rulemaking. Written comments and suggestions from the public and affected agencies concerning the collection of information are encouraged. When submitting comments on these information collections, your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of the information on those who are to respond, including through the use of any and all appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.*, permitting electronic submission of responses).

Overview of Information Collection, Application for Entrepreneur Parole, Form I–941

a. *Type of information collection:* New information collection.

b. *Abstract:* This collection will be used by individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals are subject to biometric collection in connection with the filing of the application.

c. *Title of Form/Collection:* Application for Entrepreneur Parole, Form I–941.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–941, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Applicants requesting entrepreneur parole; Businesses and/or other non-profit entities.

f. *An estimate of the total annual numbers of respondents:* 2,940.

g. *Hours per response:* The estimated hour per response for Form I–941 is 1.33 hours. The estimated hour burden per response for the biometric processing is 1.17 hours.

h. *Total Annual Reporting Burden:* The total estimated annual hour burden associated with this collection is 3,910 hours for the Form I–941 and 3,440 hours for the biometric processing, for a total of 7,350 hours.

Overview of Information Collection, Application for Travel Document Form I–131, OMB Control No. 1615–0013

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This collection will be used by dependents of individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals are subject to biometric collection in connection with the filing of the application.

c. *Title of Form/Collection:* Application for Travel Document Form I–131.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Application for Travel Document Form I–131, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Dependents of applicants requesting entrepreneur parole.

f. *An estimate of the total annual numbers of respondents:* 594,324; 3,234 additional respondents as a result of this rule.

g. *Hours per response:* The estimated hour per response for Form I–131 Supplement is 1.90 hours. The estimated hour burden per response for the biometric processing is 1.17 hours.

h. *Total Annual Reporting Burden:* 1,372,928; the total estimated additional annual hour burden associated with this collection is 143,942 hours.

Overview of Information Collection, Employment Eligibility Verification, Form I–9, OMB Control No. 1615–0047

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This form was developed to facilitate compliance with section 274A of the Immigration and Nationality Act, which prohibits the knowing employment of unauthorized aliens. This information collection is necessary for employers, agricultural recruiters and referrers for a fee, and state employment agencies to verify the identity and employment authorization of individuals hired (or recruited or referred for a fee, if applicable) for employment in the United States.

c. *Title of Form/Collection:* Employment Eligibility Verification.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–9, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Employers, employees, recruiters and referrers for a fee (limited to agricultural associations, agricultural employers, or farm labor contractors), and state employment agencies.

f. *An estimate of the total annual numbers of respondents:* 78 million employers and 78 million individuals (The total number of responses will be only 78 million responses. Each response involves an employer and an individual who is being hired).

g. *Hours per response:*

- Time Burden for Employees—20 minutes (.33 hours) total;
- Time Burden for Employers—10 minutes (.17 hours) total;
- Time Burden for Recordkeeping—5 minutes (.08 hours) total.

h. *Total Annual Reporting Burden:* Approximately 40,600,000 total annual burden hours.

Overview of Information Collection, Application for Employment Authorization, Form I–765, OMB Control No. 1615–0040

a. *Type of information collection:* Revised information collection.

b. *Abstract:* This collection will be used by individuals who file an application for entrepreneur parole under INA section 212(d)(5)(A) (8 U.S.C. 1182(d)(5)(A)) and proposed new 8 CFR 212.19. Such individuals are subject to biometric collection in connection with the filing of the application.

This form was developed for individual aliens to request employment authorization and evidence of that employment authorization. The form is being amended to add a new class of aliens eligible to apply for employment authorization: a spouse of an entrepreneur parolee described as eligible for employment authorization under this rule. Supporting documentation demonstrating eligibility must be filed with the application. The form lists examples of relevant documentation.

c. *Title of Form/Collection:* Application for Employment Authorization, Form I–765.

d. *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–765, U.S. Citizenship and Immigration Services.

e. *Affected public who will be asked or required to respond:* Spouses of applicants requesting entrepreneur parole.

f. *An estimate of the total annual numbers of respondents:* 1,984,456; 2,940 additional respondents (assuming a 1:1 ratio based on the total estimate of principal applicants for entrepreneur parole).

g. *Hours per response:* The estimated hour per response for Form I–765 is 3.42 hours. The estimated hour burden per response for the biometric processing is 1.17 hours.

h. *Total Annual Reporting Burden:* 8,196,568; the total estimated additional annual hour burden associated with this collection is 11,525 hours.

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, Immigration, Privacy, Reporting and recordkeeping requirements.

8 CFR Part 212

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, DHS is proposing to amend chapter I of title 8 of the Code of Federal Regulations as follows:

PART 103—POWERS AND DUTIES; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1365b; 31 U.S.C. 9701; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p.166; 8 CFR part 2.

■ 2. Section 103.7 is amended by adding paragraph (b)(1)(i)(FFF) to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(FFF) *Application for Entrepreneur Parole (Form I–941).* For filing an application for parole for entrepreneurs: $1,200.

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

■ 3. The authority citation for part 212 is amended to read as follows:

Authority: 6 U.S.C. 111, 202(4) and 271; 8 U.S.C. 1101 and note, 1102, 1103, 1182 and note, 1184, 1185 note (section 7209 of Pub. L. 108–458), 1187, 1223, 1225, 1226, 1227, 1255, 1359; 8 CFR part 2.

Section 212.1(q) also issued under section 702, Public Law 110–229, 122 Stat. 754, 854.

■ 4. Add § 212.19 to read as follows:

§ 212.19 Parole for entrepreneurs.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Entrepreneur* means an alien who possesses a substantial ownership interest in a start-up entity and has a central and active role in the operations of that entity, such that the alien is well-positioned, due to his or her knowledge, skills, or experience, to substantially assist the entity with the growth and success of its business. For purposes of this section, an alien may be considered to possess a substantial ownership interest if he or she possesses at least a 15 percent ownership interest in the start-up entity at the time of adjudication of the initial grant of parole and maintains at least a 10 percent ownership interest in the start-up entity at all times during the period of parole and any subsequent period of re-parole.

(2) *Start-up entity* means a U.S. business entity that was recently formed, has lawfully done business during any period of operation since its date of formation, and has substantial potential for rapid growth and job

creation. An entity that is the basis for a request for parole under this section may be considered recently formed if it was created within the 3 years immediately preceding the filing date of the alien's initial parole request. For purposes of paragraphs (a)(3) and (a)(5) of this section, an entity may be considered recently formed if it was created within the 3 years immediately preceding the receipt of the relevant grant(s), award(s), or investment(s).

(3) *Qualified government award or grant* means an award or grant for economic development, research and development, or job creation (or other similar monetary award typically given to start-up entities) made by a federal, state, or local government entity that regularly provides such awards or grants to start-up entities. This definition excludes any contractual commitment for goods or services.

(4) *Qualified investment* means an investment made in good faith, and that is not an attempt to circumvent any limitations imposed on investments under this section, of lawfully derived capital in a start-up entity that is a purchase from such entity of equity or convertible debt issued by such entity. Such an investment shall not include an investment, directly or indirectly, from the entrepreneur; the parents, spouse, brother, sister, son, or daughter of such entrepreneur; or any corporation, limited liability company, partnership, or other entity in which such entrepreneur or the parents, spouse, brother, sister, son, or daughter of such entrepreneur directly or indirectly has any ownership interest.

(5) *Qualified investor* means an individual who is a U.S. citizen or lawful permanent resident of the United States, or an organization that is located in the United States and operates through a legal entity organized under the laws of the United States or any state, that is majority owned and controlled, directly and indirectly, by U.S. citizens or lawful permanent residents of the United States, provided such individual or organization regularly makes substantial investments in start-up entities that subsequently exhibit substantial growth in terms of revenue generation or job creation. The term "qualified investor" shall not include an individual or organization that has been permanently or temporarily enjoined from participating in the offer or sale of a security or in the provision of services as an investment adviser, broker, dealer, municipal securities dealer, government securities broker, government securities dealer, bank, transfer agent or credit rating agency, barred from association with any entity involved in the offer or sale of securities or provision of such services, or otherwise found to have participated in the offer or sale of securities or provision of such services in violation of law. For purposes of this section, such an individual or organization may be considered a qualified investor if, during the preceding 5 years:

(i) The individual or organization made investments in start-up entities in exchange for equity or convertible debt in at least 3 separate calendar years comprising a total in such 5-year period of no less than $1,000,000; and

(ii) Subsequent to such investment by such individual or organization, at least 2 such entities each created at least 5 qualified jobs or generated at least $500,000 in revenue with average annualized revenue growth of at least 20 percent.

(6) *Qualified job* means full-time employment located in the United States that has been filled for at least 1 year by one or more qualifying employees.

(7) *Qualifying employee* means a U.S. citizen, a lawful permanent resident, or other immigrant lawfully authorized to be employed in the United States, who is not an entrepreneur of the relevant start-up entity or the parent, spouse, brother, sister, son, or daughter of such an entrepreneur. This definition shall not include independent contractors.

(8) *Full-time employment* means paid employment in a position that requires a minimum of 35 working hours per week. This definition does not include combinations of part-time positions even if, when combined, such positions meet the hourly requirement per week.

(9) *U.S. business entity* means any corporation, limited liability company, partnership, or other entity that is organized under federal law or the laws of any state, and that conducts business in the United States, that is not an investment vehicle primarily engaged in the offer, purchase, sale or trading of securities, futures contracts, derivatives or similar instruments.

(10) *Material change* means any change in facts that could reasonably affect the outcome of the determination whether the entrepreneur provides, or continues to provide, a significant public benefit to the United States. Such changes include, but are not limited to, the following: Any criminal charge, conviction, plea of no contest, or other judicial determination in a criminal case concerning the entrepreneur or start-up entity; any complaint, settlement, judgment, or other judicial or administrative determination concerning the entrepreneur or start-up entity in a legal or administrative proceeding brought by a government entity; any settlement, judgment, or other legal determination concerning the entrepreneur or start-up entity in a legal proceeding brought by a private individual or organization other than proceedings primarily involving claims for damages not exceeding 10 percent of the current assets of the entrepreneur or start-up entity; a sale or other disposition of all or substantially all of the start-up entity's assets; the liquidation, dissolution or cessation of operations of the start-up entity; the voluntary or involuntary filing of a bankruptcy petition by or against the start-up entity; and any significant change to the entrepreneur's role in or ownership and control in the start-up entity or any other significant change with respect to ownership and control of the start-up entity.

(b) *Initial parole*—(1) *Filing of initial parole request form.* An alien seeking an initial grant of parole as an entrepreneur of a start-up entity must file an Application for Entrepreneur Parole (Form I–941, or successor form) with USCIS, with the required fees (including biometric services fees), and supporting documentary evidence in accordance with this section and the form instructions, demonstrating eligibility as provided in paragraph (b)(2) of this section.

(2) *Criteria for consideration.* (i) *In general.* An alien may be considered for parole under this section if the alien demonstrates that a grant of parole will provide a significant public benefit to the United States based on his or her role as an entrepreneur of a start-up entity.

(ii) *General criteria.* An alien may meet the standard described in paragraph (b)(2)(i) of this section by providing a detailed description, along with supporting evidence:

(A) Demonstrating that the alien is an entrepreneur as defined in paragraph (a)(1) of this section and that his or her entity is a start-up entity as defined in paragraph (a)(2) of this section; and

(B) Establishing that the alien's entity has:

(*1*) Received, within 365 days immediately preceding the filing of an application for initial parole, a qualified investment amount of at least $345,000 from one or more qualified investors; or

(*2*) Received, within 365 days immediately preceding the filing of an application for initial parole, an amount of at least $100,000 through one or more qualified government awards or grants.

(iii) *Alternative criteria.* An alien who satisfies the criteria in paragraph (b)(2)(ii)(A) of this section and partially meets one or both of the criteria in paragraph (b)(2)(ii)(B) of this section may alternatively meet the standard described in paragraph (b)(2)(i) of this section by providing other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

(c) *Additional periods of parole*—(1) *Filing of re-parole request form.* Prior to the expiration of the initial period of parole, an entrepreneur parolee may request an additional period of parole based on the same start-up entity that formed the basis for his or her initial period of parole granted under this section. To request such parole, an entrepreneur parolee must timely file the Application for Entrepreneur Parole (Form I–941, or successor form) with USCIS, with the required fees (including biometric services fees), and supporting documentation in accordance with the form instructions, demonstrating eligibility as provided in paragraph (c)(2) of this section.

(2) *Criteria for consideration*—(i) *In general.* An alien may be considered for re-parole under this section if the alien demonstrates that a grant of parole will continue to provide a significant public benefit to the United States based on his or her role as an entrepreneur of a start-up entity.

(ii) *General criteria.* An alien may meet the standard described in paragraph (c)(2)(i) by providing a detailed description, along with supporting evidence:

(A) Demonstrating that the alien continues to be an entrepreneur as defined in paragraph (a)(1) of this section and that his or her entity continues to be a start-up entity as defined in paragraph (a)(2) of this section; and

(B) Establishing that the alien's entity has:

(*1*) Received at least $500,000 in qualifying investments, qualified government grants or awards, or a combination of such funding, during the initial parole period;

(*2*) Created at least 10 qualified jobs with the start-up entity during the initial parole period; or

(*3*) Reached at least $500,000 in annual revenue and averaged 20 percent in annual revenue growth during the initial parole period.

(iii) *Alternative criteria.* An alien who satisfies the criteria in paragraph (c)(2)(ii)(A) of this section and partially meets one or more of the criteria in paragraph (c)(2)(ii)(B) may alternatively meet the standard described in paragraph (c)(2)(i) of this section by providing other reliable and compelling evidence of the start-up entity's substantial potential for rapid growth and job creation.

(d) *Discretionary authority; decision; appeals and motions to reopen.* (1) *Discretionary authority.* DHS may grant parole under this section in its sole discretion on a case-by-case basis if the Department determines, based on the totality of the evidence, that an applicant's presence in the United States will provide a significant public benefit and that he or she otherwise merits a favorable exercise of discretion. In determining whether an alien's presence in the United States will provide a significant public benefit and whether the alien warrants a favorable exercise of discretion, USCIS will consider and weigh all evidence, including any derogatory evidence or information, such as but not limited to, evidence of criminal activity or national security concerns.

(2) *Initial parole.* DHS may grant an initial period of parole based on the start-up entity listed in the request for parole for a period of up to 2 years from the date the request is approved by USCIS. Approval by USCIS of such a request must be obtained before the alien may appear at a port of entry to be granted parole, in lieu of admission.

(3) *Re-parole.* DHS may re-parole an entrepreneur for one additional period of up to 3 years from the date of the expiration of the initial parole period. If the entrepreneur is in the United States at the time that USCIS approves the request for re-parole, such approval shall be considered a grant of re-parole. If the alien is outside the United States at the time that USCIS approves the request for re-parole, the alien must appear at a port of entry to be granted parole, in lieu of admission.

(4) *Appeals and motions to reopen.* There is no appeal from a denial of parole under this section. USCIS will not consider a motion to reopen or reconsider a denial of parole under this section. On its own motion, USCIS may reopen or reconsider a decision to deny the Application for Entrepreneur Parole (Form I–941, or successor form), in accordance with 8 CFR 103.5(a)(5).

(e) *Payment of biometric services fee and collection of biometric information.* An alien seeking parole or re-parole under this section will be required to pay the biometric services fee as prescribed by 8 CFR 103.7(b)(1)(i)(C). An alien seeking an initial grant of parole will be required to submit biometric information. An alien seeking re-parole may be required to submit biometric information.

(f) *Limitations.* No more than three entrepreneurs may be granted parole under this section based on the same start-up entity. An alien shall not receive more than one initial grant of entrepreneur parole or more than one additional grant of entrepreneur re-parole based on the same start-up entity, for a maximum period of parole of five years.

(g) *Employment authorization.* An entrepreneur who is paroled into the United States pursuant to this section is authorized for employment with the start-up entity incident to the conditions of his or her parole.

(h) *Spouse and children.* (1) The entrepreneur's spouse and children who are seeking parole as derivatives of such entrepreneur must individually file an Application for Travel Document (Form I–131). Such application must also include evidence that the derivative has a qualifying relationship to the entrepreneur and otherwise merits a grant of parole in the exercise of discretion. A biometric services fee is required to be filed with the application. Such spouse or child will be required to appear for collection of biometrics in accordance with the form instructions or upon request.

(2) The spouse and children of an entrepreneur granted parole under this section may be granted parole under this section for no longer than the period of parole granted to such entrepreneur.

(3) The spouse of the entrepreneur parolee, after being paroled into the United States, may be eligible for employment authorization on the basis of parole under this section. To request employment authorization, an eligible spouse paroled into the United States must file an Application for Employment Authorization (Form I–765, or successor form), in accordance with 8 CFR 274a.13 and form instructions. An Application for Employment Authorization must be accompanied by documentary evidence establishing eligibility, including evidence of the spousal relationship.

(4) Notwithstanding 8 CFR 274a.12(c)(11), a child of the entrepreneur parolee may not be authorized for and may not accept employment on the basis of parole under this section.

(i) *Conditions on parole.* As a condition of parole under this section, a parolee must maintain household income that is greater than 400 percent of the federal poverty line for his or her household size as defined by the Department of Health and Human Services. USCIS may impose other such reasonable conditions in its sole discretion with respect to any alien approved for parole under this section, and it may request verification of the parolee's compliance with any such condition at any time. Violation of any condition of parole may lead to termination of the parole in accordance with paragraph (k) of this section or denial of re-parole.

(j) *Reporting of material changes.* An alien granted parole under this section must immediately report any material change(s) to USCIS. If the entrepreneur will continue to be employed by the start-up entity and maintains at least a 10 percent ownership interest in the start-up entity, the entrepreneur must submit a new Application for Entrepreneur Parole (Form I–941, or successor form) with filing fee (not including any biometrics fees) and supporting documentary evidence to notify USCIS of the material change(s). The entrepreneur parolee must immediately notify USCIS in writing if he or she will no longer be employed by the start-up entity or ceases to possess at least a 10 percent ownership stake in the start-up entity.

(k) *Termination of parole*—(1) *In general.* DHS may, in its discretion, terminate parole granted under this section at any time and without prior notice or opportunity to respond if it determines that the alien's continued parole in the United States no longer provides a significant public benefit. Alternatively DHS may, in its discretion, provide the alien notice and an opportunity to respond prior to terminating the alien's parole under this section.

(2) *Automatic termination.* Parole granted under this section will be automatically terminated without notice at the expiration of the time for which parole was authorized, unless the alien timely files a non-frivolous application for re-parole. Parole granted under this section may be automatically terminated when USCIS receives written notice from the entrepreneur parolee that he or she will no longer be employed by the start-up entity or ceases to possess at least a 10 percent ownership stake in the start-up entity in accordance with paragraph (j) of this section. Additionally, parole of the spouse or child of the entrepreneur will be automatically terminated without notice if the parole of the entrepreneur has been terminated. If parole is terminated, any employment authorization based on that parole is automatically revoked.

(3) *Termination on notice.* USCIS may terminate on notice or provide the entrepreneur or his or her spouse or children, as applicable, written notice of its intent to terminate parole if USCIS believes that:

(i) The facts or information contained in the request for parole were not true and accurate;

(ii) The alien failed to timely file or otherwise comply with the material change reporting requirements in this section;

(iii) The entrepreneur parolee is no longer employed in a central and active role by the start-up entity or ceases to possess at least a 10 percent ownership stake in the start-up entity;

(iv) The alien otherwise violated the terms and conditions of parole; or

(v) Parole was erroneously granted.

(4) *Notice and decision.* A notice of intent to terminate issued under this paragraph should generally identify the grounds for termination of the parole and provide a period of up to 30 days for the alien's written rebuttal. The alien may submit additional evidence in support of his or her rebuttal, when applicable, and USCIS will consider all relevant evidence presented in deciding whether to terminate the alien's parole. Failure to timely respond to a notice of intent to terminate will result in termination of the parole. When a charging document is served on the alien, the charging document will constitute written notice of termination of parole (if parole has not already been terminated), unless otherwise specified. Any further immigration and removal actions will be conducted in accordance with the Act and this chapter. The decision to terminate parole may not be appealed. USCIS will not consider a motion to reopen or reconsider a decision to terminate parole under this section. On its own motion, USCIS may reopen or reconsider a decision to terminate.

(l) *Increase of investment and revenue amount requirements.* The investment and revenue amounts in this section will be automatically adjusted every 3 years by the Consumer Price Index and posted on the USCIS Web site at *www.uscis.gov.* Investment and revenue amounts adjusted under this paragraph will apply to all applications filed on or after the beginning of the fiscal year for which the adjustment is made.

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 5. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; 48 U.S.C. 1806; 8 CFR part 2.

■ 6 Section 274a.2 is amended by:

■ (a) Revising paragraphs (b)(1)(v)(A)(*5*) and (b)(1)(v)(C)(*2*);

■ (b) Removing paragraph (b)(1)(v)(C)(*3*); and

■ (c) Redesignating paragraphs (b)(1)(v)(C)(4) through (8) as paragraphs (b)(1)(v)(C)(3) *through* (7).

The revision reads as follows:

§ 274a.2 Verification of identity and employment authorization.

* * * * *

(b) * * *

(1) * * *

(v) * * *

(A) * * *

(*5*) In the case of an individual who is employment-authorized incident to status or parole with a specific employer, a foreign passport with an Arrival/Departure Record, Form I–94 (as defined in 8 CFR 1.4) or Form I–94A, bearing the same name as the passport and containing an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole.

* * * * *

(C) * * *

(*2*) Certification or report of birth issued by the Department of State, including Forms FS–545, DS–1350, FS–240, or successor forms;

* * * * *

■ 7. Section 274a.12 is amended by:

■ a. Revising paragraph (b) introductory text,

■ b. Adding and reserving new paragraphs (b)(25) through (36);

■ c. Adding a new paragraph (b)(37);

■ d. Revising paragraph (c)(11);

■ e. Adding and reserving new paragraphs (c)(27) through (33);

■ f. Adding a new paragraph (c)(34).

The revisions and additions read as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(b) *Aliens authorized for employment with a specific employer incident to status or parole.* The following classes of aliens are authorized to be employed in the United States by the specific employer and subject to any restrictions described in the section(s) of this chapter indicated as a condition of their parole, or admission in, or subsequent change to, such classification. An alien in one of these classes is not issued an employment authorization document by DHS:

* * * * *

(25)–(36) [Reserved] (37) An alien paroled into the United States as an entrepreneur pursuant to 8 CFR 212.19 for the period of authorized parole. An entrepreneur who has timely filed a non-frivolous application requesting re-parole with respect to the same start-up entity in accordance with 8 CFR 212.19 prior to the expiration of his or her parole, but whose authorized parole period expires during the pendency of such application, is authorized to continue employment with the same start-up entity for a period not to exceed 240 days beginning on the date of expiration of parole. Such authorization shall be subject to any conditions and limitations on such expired parole. If DHS adjudicates the application prior to the expiration of this 240-day period and denies the application for re-parole, the employment authorization under this paragraph shall automatically terminate upon notification to the alien of the denial decision.

* * * * *

(c) * * *

(11) Except as provided in § 274a.12(b)(37) and (c)(34) and § 212.19(h)(4) of this chapter, an alien paroled into the United States temporarily for urgent humanitarian reasons or significant public benefit pursuant to section 212(d)(5) of the Act.

* * * * *

(27)–(33) [Reserved]

(34) A spouse of an entrepreneur parolee described as eligible for employment authorization in § 212.19(h)(3) of this chapter.

* * * * *

Jeh Charles Johnson,

Secretary of Homeland Security.

[FR Doc. 2016–20663 Filed 8–26–16; 1:00 pm]

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 20, 201, 207, et al.
Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 514, 515, 601, 607, and 1271

[Docket No. FDA–2005–N–0464 (formerly Docket No. 2005N–0403)]

RIN 0910–AA49

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing drug establishment registration and drug listing. These amendments reorganize, modify, and clarify current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products, and animal drugs. The final rule requires electronic submission, unless waived in certain circumstances, of registration and listing information. This rulemaking pertains to finished drug products and to active pharmaceutical ingredients (APIs) alone or together with one or more other ingredients. The final rule describes how and when owners or operators of establishments at which drugs are manufactured or processed must register their establishments with FDA and list the drugs they manufacture or process. In addition, the rule makes certain changes to the National Drug Code (NDC) system. We are taking this action to improve management of drug establishment registration and drug listing requirements and make these processes more efficient and effective for industry and for us. This action also supports implementation of the electronic prescribing provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the availability of current drug labeling information through DailyMed, a computerized repository of drug information maintained by the National Library of Medicine.

DATES: This rule is effective on November 29, 2016. See section IV for compliance dates.

FOR FURTHER INFORMATION CONTACT:

For information pertaining to human drug products: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993, 301–796–2173.

For information pertaining to human biological drug products or human cells, tissue, and cellular and tissue-based products (HCT/Ps) regulated solely under section 361 of the Public Health Service Act: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

For information pertaining to animal drug products: Charise Kasser, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rm. 2626, Rockville, MD 20855, 240–402–6816; or Isabel Pocurull, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rm. 2636, Rockville, MD 20855, 240–402–5877.

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Executive Summary

Purpose of the Regulatory Action

This final rule amends FDA's longstanding regulations governing drug establishment registration and drug listing. The amendments are aimed at modernizing these regulations and improving efficiency and reliability for FDA and drug manufacturers. These amendments also bring FDA's regulations governing drug establishment registration and listing into conformance with section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) as amended by the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85) and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144).

Since the 1962 Kefauver Harris amendments to the FD&C Act (Pub. L. 87–781), drug manufacturers have been required to register their establishments with FDA annually. Among other things, drug establishment registration identifies establishments for inspection by FDA. In 1973, the FD&C Act was further amended to require each registered establishment to submit a list of drugs it manufactures. FDA's regulations implementing these requirements are found in part 207 (21 CFR part 207) (pertaining to drugs and biological products generally) and part 607 (21 CFR part 607) (pertaining to blood and blood products). Manufacturers of HCT/Ps register and list either under part 207, part 807 (21 CFR 807), or under part 1271 (21 CFR part 1271), issued under authority of the Public Health Service Act (PHS Act), depending on the type of HCT/P product they manufacture.

The amendments to parts 207 and 607 adopted by this final rule modernize those regulations and bring them into conformance with section 510 of the FD&C Act following recent amendments.

Summary of the Major Provisions of the Regulatory Action

This final rule requires electronic submission, unless waived in certain circumstances, of drug establishment registration and listing information. The electronic submission requirement is consistent with FDAAA and with current practice.

The rule makes clear that the establishment registration and listing obligation rests with persons who manufacture, repack, relabel, or salvage drug products. The rule does not require persons who act only as private label distributors of drug products to register establishments or list drugs, but allows them to submit drug listing information as agents acting on behalf of persons who manufacture, repack, relabel, or salvage drug products. The amendments make several adjustments to the timing and substance of the submission of information to register a drug establishment and list drugs manufactured, repacked, relabeled, or salvaged at the establishment. The amendments also update longstanding regulatory provisions governing FDA disclosure of drug registration and listing information, stating that with certain exceptions, establishment registration and drug listing information is generally available for public disclosure.

This final rule does not include certain aspects of the proposed rule that were opposed by many who submitted comments. Features of the proposed rule that have not been finalized include most significantly: (1) A requirement that FDA, not registrants, develop national drug codes (NDCs) for assignment to listed drugs and (2) a requirement that the NDC appear in human-readable form on the label of each listed drug and provisions that would have defined the appropriate NDC for that purpose. As discussed in section III, revisions to the FD&C Act require human-readable NDCs on certain drug labels.

Benefits and Costs

All incremental costs from the final rule are one-time costs, except for registrants' annually recurring costs of certifying no change to listings upon annual registration for part 207 registrants. We estimate one-time total costs of $59.7 million and recurring costs of $0.5 million. These costs represent total annualized costs of $9 million when calculated at a 7-percent discount rate over 10 years, and $7.5 million when calculated using a 3-percent discount rate. The largest cost elements will be for registrants reading and understanding the final rule and making changes to their standard operating procedures.

SUMMARY OF TOTAL INCREMENTAL COST OF THE FINAL RULE

[$ millions]

Affected firms	One-time costs	Recurring costs (annual)	Total costs annualized at 7%	Total costs annualized at 3%
Drugs and biological products (part 207)	$48.9	$0.5	$7.5	$6.2
Human blood products (part 607)	5.1	N/A	0.7	0.6
Human cell and tissue products (part 1271)	5.7	N/A	0.8	0.7
Total[1]	59.7	0.5	9.0	7.5

[1] Total costs are annualized over a 10-year period. Recurring costs include only annual time costs of certifying that there are no changes to listings; these costs are unique to part 207. All estimates reflect rounded 2014 dollars.

By codifying the statutory requirements of FDAAA and FDASIA, the final rule clarifies and completes the modernization of our electronic registration and listing systems. Thus, the final rule will improve management of the establishment registration and drug listing requirements and make these processes more efficient and effective for industry and for us. The final rule also supports implementation of the electronic prescribing provisions of the MMA and the availability of current drug labeling information through DailyMed, a computerized repository of drug information maintained by the National Library of Medicine.

I. Background

In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA proposed to amend its regulations governing drug establishment registration and drug listing in part 207 (proposed rule). The proposed rule included ancillary amendments to parts 20, 201, 314, 514, 515, 601, 607, and 1271 (21 CFR parts 20, 201, 314, 514, 515, 601, 607, and 1271). These amendments reorganize, modify, and clarify current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products, and animal drugs. The proposed rule and the final rule both specify that drug establishment registration and drug listing information generally must be submitted to FDA electronically.

After the proposed rule was published, FDAAA was adopted into law. FDAAA amended section 510(p) of the FD&C Act to require electronic submission of drug establishment registration and listing information, unless FDA waives the electronic submission requirement in individual cases. In June 2009, FDA announced publication of a guidance for industry on "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing" consistent with FDAAA (74 FR 26248, June 1, 2009, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) (the electronic registration and listing guidance). This guidance applied to establishment registration and listing required under part 207. It did not apply to information required solely under part 607 (blood and blood products), part 807 (devices), or part 1271 (human cells, tissues, and cellular and tissue-based products). FDA generally stopped receiving drug establishment registration and listing information required under part 207 submitted on paper in June 2009, allowing paper submissions only if supported by a waiver from the electronic submission requirement in individual cases. This final rule is consistent with the electronic submission provisions of FDAAA.

FDASIA made further amendments to section 510 of the FD&C Act in 2012 to specify that:

- Annual registration of establishments takes place during the period beginning on October 1 and ending on December 31.
- The information registrants supply for annual registration includes a Unique Facility Identifier (UFI) for the establishment and includes a point-of-contact email address.

This final rule includes changes to the proposed rule consistent with these statutory provisions. The electronic registration and listing guidance stated that FDA intended to use the Data Universal Numbering System (DUNS) number, assigned and managed by Dun

& Bradstreet, as a registration number. In 2014, FDA announced publication of a guidance for industry on "Specifications of the Unique Facility Identifier (UFI) System for Drug Establishment Registration," (79 FR 65977, November 6, 2014, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)), in which FDA specified the DUNS number as the preferred UFI.

II. Overview of the Final Rule Including Changes to the Proposed Rule

A. Overview

The final rule adopts significant amendments to FDA's regulations governing drug registration and listing. It modernizes these regulations to require electronic submission of drug establishment registration and listing information and to otherwise match current statutory requirements and FDA's information needs.

The final rule:

- Makes minor technical amendments to §§ 20.100, 20.116, and 201.1 (updating citations to regulations in part 207).
- Removes from § 201.2 a statement about the manner in which NDCs are displayed on drug labels.
- Amends § 201.25 to allow an FDA Center Director to approve an additional bar code standard or format.
- Revises part 207 significantly.
- Amends § 314.81(b)(3)(iv) (requiring holders of approved new drug applications (NDAs) to report the withdrawal of approved drug products from sale) to make it consistent with part 207.
- Makes a minor conforming amendment to § 314.125(b)(11) (stating FDA may refuse to approve a new drug application if the drug will be manufactured in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the FD&C Act and part 207).
- Adds new § 514.111(a)(12) stating FDA will refuse to approve a new animal drug application if the drug will be produced in whole or in part in an establishment that is not registered and is not exempt from registration under section 510 of the FD&C Act and part 207.
- Makes a minor technical amendment to § 515.10(b)(8), updating a reference to the regulations in part 207.
- Adds new § 601.2(f) requiring holders of biologics license applications (BLAs) to report to FDA electronically in accordance with part 207 the withdrawal from sale of licensed biological products.
- Amends part 607 (ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS) consistent with the amendments to part 207, to require electronic submission of establishment registration and listing information.
- Amends part 1271 (HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS) to require electronic submission of establishment registration and listing information, to state that manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act (42 U.S.C. 262) or under the FD&C Act are subject to registration and listing under part 207 or part 807, and to make other revisions consistent with the amendments to part 207.

B. Changes to the Proposed Rule

The final rule has been revised in response to comments received on the proposed rule. Our responses are discussed in section III. The final rule also includes several minor editorial revisions. The final rule makes the changes summarized in table 1.

TABLE 1—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE

21 CFR Section in final rule	Description of change from proposed rule
201.2	Labeling. • Does not include proposed revisions to § 201.2 requiring human-readable NDCs on labels.
201.25	Bar code label requirements. • Revises § 201.25(c)(1) to accommodate alternatively formatted NDCs in bar codes. • Does not include other proposed amendments to § 201.25.
207.1	Definitions. • Includes definitions for the terms "finished drug product," "unfinished drug product," "bulk drug substance," "private label distribution," "registrant," and "outsourcing facility" not included in the proposed rule. • States that the definitions and interpretations of terms in sections 201 (21 U.S.C. 321) and 510 of the FD&C Act apply to the terms used in part 207, if not otherwise defined in § 207.1. • Includes revised definitions of the terms "active pharmaceutical ingredient," "commercial distribution," "content of labeling," "importer," "manufacture," "private label distributor," "relabel," "repack," and "representative sampling of any other labeling".
207.9	Who does this part cover? • Clarifies that private label distributors are subject to part 207 (because they must have labeler codes). • States that all drugs regulated under a BLA, except human blood or blood products regulated under part 607, are subject to part 207 and clarifies that for this purpose certain products are not included in the phrase "human whole blood and blood products". • States that HCT/Ps regulated as drugs under section 505 of the FD&C Act (21 U.S.C. 355) or section 351 of the PHS Act are subject to part 207.
207.13	Who is exempt from the registration and listing requirements? • Generally exempts from registration and listing individuals or establishments engaged solely in recovering cells or tissues to become components of a biological product at a registered establishment. • Eliminates a reference to salvagers of inactive ingredients because salvaging, as defined, is performed only on finished drug products. • Revises § 207.13 to clarify the applicability of part 207 to medicated feeds. • Revises § 207.13 to remove a reference to HCT/Ps made unnecessary by revisions to § 207.9. • Adds an exemption for outsourcing facilities registered under section 503B of the FD&C Act (21 U.S.C. 353b) so as to avoid duplicative registration for those entities. • Retains the previous establishment registration exemptions for certain drugs entering foreign trade zones and certain drugs imported for export.
207.17	Who must register?

TABLE 1—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE—Continued

21 CFR Section in final rule	Description of change from proposed rule
	• Revises § 207.17(b) to state that FDA will accept establishment registration or listing information submitted by a private label distributor if it is acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs.
207.25	What information is required for registration? • Revises proposed § 207.25 to include the UFI required as part of establishment registration under FDASIA.
207.29	What are the requirements for reviewing and updating registration information? • Revises § 207.29 to specify that registrants must review and update registration information between October 1 and December 31 each year, consistent with FDASIA.
207.33	What is the National Drug Code (NDC), how is it assigned, and what are its requirements? • Allows for 10- or 11-digit NDCs, consistent with a longstanding statement in § 207.35(b)(2)(i), as it read prior to this final rule, that FDA will expand the NDC labeler code from 5 to 6 numeric characters when the available 5-character code combinations are exhausted. • States that registrants will propose NDCs for assignment by FDA. • Includes formatting requirements for registrants to follow when formulating their own proposed NDCs. • Allows for alternatively formatted NDCs for certain HCT/Ps. • Explains how a labeler code can be obtained. • Allows registrants to reserve an NDC for a drug product under development. • Eliminates proposed § 207.33(c). (What information must a manufacturer submit before we will assign an NDC number to a drug?) • Adds some information elements described in proposed § 207.33(c) to the drug listing information now described in § 207.49 (Added to the listing information required under § 207.49 are the names of inactive ingredients in the listed drug and in the case of an unfinished drug, the number assigned to the Drug Master File or Veterinary Master File, if any, that describes the manufacture of the drug). • The option to submit an approved U.S. application number instead of a list of inactive ingredients for a finished drug product (as proposed in § 207.33(c)) is not retained in § 207.49 of this final rule.
207.35	What changes require a new NDC? • Introduces new § 207.35 to more clearly explain what changes to drugs require a new NDC and does not include inactive ingredient changes in this section.
207.37	What restrictions pertain to the use of the NDC? • Revises § 207.37 to state that a product may be deemed to be misbranded if an NDC is used improperly.
207.41	Who must list drugs and what drugs must they list? • Revises § 207.41 to clarify the manner in which human drugs that are manufactured, repacked, or relabeled for private label distribution are listed.
207.45	When, after initial registration of an establishment, must drug listing information be submitted? • Revises § 207.45 to state that drug listing must take place no later than 3 calendar days after initial registration of an establishment, rather than "at the time of" initial registration.
207.49	What listing information must a registrant submit for a drug it manufactures? • Revises § 207.49 to reflect that registrants will propose their own NDCs under the final rule. • Eliminates the requirement of proposed §§ 207.49(f), 207.53(c), and 207.54(b)(4) (which would have required foreign establishments to identify importers when listing drugs they manufacture, repack, relabel, or salvage). (This is now reported only as establishment registration information for foreign establishments.). • Expands the language of proposed § 207.49(d) (now § 207.49(a)(11)) to make clear that a registrant's own establishment(s) must be identified in drug listing information as well as other establishments involved in the production of unfinished drugs received by the registrant and to require identification of all such establishments using their UFIs. • Removes from proposed § 207.49 the option to provide an approved U.S. application number instead of labeling. • Revises § 207.49 (also §§ 207.1 and 207.53) to categorize certain drug products according to whether they are subject to sections 505 or 512 of the FD&C Act (21 U.S.C. 355 or 360b) or section 351 of the PHS Act, rather than whether registrants regard them as subject to those provisions. • Adds §§ 207.49(a)(15)(iv) and 207.53(d)(4) to require the submission of labels for listed drugs not elsewhere described in §§ 207.49(a)(14) and 207.53(d). • Clarifies in new §§ 207.49(a)(15) and 207.53(f) the information a registrant must submit when listing a human drug manufactured for private label distribution. • Adds § 207.49(b) to describe drug listing information that is requested of registrants but not required. • Adds § 207.49(a)(2) so that drug listing information includes package size and type.
207.53	What listing information must a registrant submit for a drug that it repacks or relabels? • Shifts from proposed § 207.33(d)(1)(iii) to new § 207.53(b) the requirement that for a repacked or relabeled drug, registrants identify the NDC assigned to the finished drug received by the registrant for repacking or relabeling and exempts repackaged medical gases from this requirement. • Requires identification of establishments where repacking, or relabeling is performed based on their UFIs rather than by their registration numbers. • Clarifies that all current labeling (new labeling) for a repacked or relabeled drug must be submitted, not only the changed labeling. • Specifies that for animal drugs subject to section 512 of the FD&C Act, all current *labeling* is submitted, whereas a copy of the current *label,* and other information, is submitted for other animal drugs.
207.54	What listing information must a registrant submit for a drug that it salvages? • Requires identification of establishments where salvaging is performed by their UFIs rather than by their registration numbers. • Deletes references to salvaged drugs distributed by private label distributors.
207.57	What information must registrants submit when updating listing information and when? • Revises proposed § 207.57 to improve clarity and to delete the proposed requirement that registrants routinely update information provided under § 207.55.

TABLE 1—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE—Continued

21 CFR Section in final rule	Description of change from proposed rule
	• Allows registrants to submit a blanket "no changes" certification applicable to listing information they have previously submitted electronically, rather than making product-by-product "no changes" certifications for individual listed drugs.
207.61	How is registration and listing information provided to FDA? • Revises § 207.61 to improve clarity, to state that we may periodically issue guidance on electronic registration and listing, and to clarify that when foreign language labeling is used under § 201.15(c), the content of labeling must be submitted in that foreign language along with an accurate English translation. • Removes the option to submit advertisements and certain labeling in paper format, consistent with the electronic submission requirement of section 510(p) of the FD&C Act, as amended by FDAAA.
207.65	How can a waiver of the electronic submission requirement be obtained? • Clarifies that requests for waivers of the electronic submission requirement cannot be relied upon until FDA grants them. • States more broadly the conditions under which FDA will grant waiver requests. • Specifies that waiver requests must be submitted in writing and must state reasons why electronic submission is not reasonable for the registrant. • States that FDA will specify terms of waivers and may limit their duration.
207.69	What are the requirements for an official contact and a United States agent? • Revises proposed § 207.69 to state that designated official contacts and United States agents are both responsible for reviewing, disseminating, routing, and responding to all communications from FDA, including emergency communications.
207.77	What legal status is conferred by registration and listing? • Includes minor revisions to improve clarity and mentions the UFI that will be used to identify establishments.
207.81	What registration and listing information will FDA make available for public disclosure? • Reorganizes § 207.81 so that registration and listing information that will be disclosed is described in paragraph (a), and exceptions are described in paragraphs (b) and (c). • Categorizes updated drug listing information submitted under § 207.57 as generally disclosable. • Adds § 207.81(b)(2) to make explicit that FDA will generally not disclose the names of inactive ingredients in listed drug products if the registrant makes a valid assertion of confidentiality. • Categorizes the information submitted to reserve an NDC under new § 207.33(d)(3) as generally not disclosable. • Categorizes the identities of the establishments involved in manufacturing, repacking, relabeling, or salvaging listed drugs as generally not disclosable. • Categorizes as generally not disclosable the NDC assigned to an unfinished drug received by a registrant for use in the manufacture of a listed drug reported under § 207.49(a)(12) (*i.e.*, the association between the unfinished drug and the listed drug is generally not disclosable). • No longer categorizes the NDC assigned to a drug immediately before it is received by a registrant for salvaging as generally not disclosable (because the NDC assigned to a drug does not change when a drug is merely salvaged and not also repackaged or relabeled).
314.81	Other postmarketing reports (reporting the discontinuation of a drug that is the subject of an approved NDA). • Renumbers proposed § 314.81(b)(3)(iii) as § 314.81(b)(3)(iv) and revises this section to provide for electronic or written submissions in certain circumstances, under both paragraphs (a) and (b).
601.2(f)	Applications for biologics licenses (reporting the discontinuation of a drug that is licensed under a BLA). • Revises proposed § 601.2(f) to reference the electronic submission requirement of § 207.61 and the waiver provision of § 207.65 and to clarify that the date on which the product is expected to be no longer in commercial distribution must be reported rather than the "date of withdrawal from sale".
607.1	Scope (Establishment registration and product listing for manufacturers of human blood and blood products.) • Adds a new scope provision (§ 607.1) to part 607 for clarity.
607.3	Definitions (Establishment registration and listing for blood and blood products). • Adds a definition of "foreign". • Revises the proposed definition of "importer".
607.22	How to register blood product establishments and list blood products. • Revises proposed § 607.22 to remove references to Form FDA 2830 and to state that blood product establishment registration and blood product listing must be transmitted to FDA electronically through the Blood Establishment Registration and Product Listing system, unless FDA waives the electronic submission requirement in individual cases.
607.25	Information required for establishment registration and blood product listing. • Removes references to Form FDA 2830. • Requires submission of a UFI when registering blood and blood product establishments along with a registration number if previously assigned by FDA. • Adds the UFI of the parent establishment to blood product listing information required under § 607.25(b)(3).
607.26	Amendments to establishment registration. • Revises § 607.26 regarding amendments to establishment registration to reference the Blood Establishment Registration and Listing System in place of Form FDA 2830. • Clarifies that 5 days refers to 5 calendar days in this section.
607.30	Updating blood product listing information. • Revises § 607.30 regarding updates to blood product listing information to reference the Blood Establishment Registration and Listing System in place of Form FDA 2830.
607.37	Public disclosure of establishment registration and blood product listing information. • Revises § 607.37 to remove references to Form FDA 2830. • Structures § 607.37 in a way that matches § 207.81 (public disclosure of drug registration and listing information).
607.40	Establishment registration and blood product listing requirements for foreign blood product establishments. • Retains the exemptions applicable to foreign trade zones and products imported under section 801(d)(4) of the FD&C Act (21 U.S.C. 381(d)(4)).

TABLE 1—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE—Continued

21 CFR Section in final rule	Description of change from proposed rule
	• Revises proposed § 607.40 to state more broadly the circumstances under which FDA will waive the electronic submission requirement for foreign blood product establishments.
607.80	Applicability of part 607 to licensed devices. • Adds a new § 607.80 clarifying the applicability of part 607 to certain licensed devices.
1271.1	What are the purpose and scope of this part? (HCT/Ps) • Adds the word "electronic" in place of "unified" in § 1271.1.
1271.3	How does FDA define important terms in this part? • Revises the definition of "importer" in proposed § 1271.3(mm) to include "at the time of entry".
1271.20	If my HCT/Ps do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions, what regulations apply? • Adds a further amendment to § 1271.20 to indicate that subpart B of part 1271 (procedures for registration and listing) does not apply to HCT/Ps that do not meet the criteria set out in § 1271.10(a). (In other words, HCT/Ps not regulated solely under section 361 of the PHS Act are subject to registration and listing under part 207 or part 807 rather than part 1271.)
1271.25	What information is required for establishment registration and HCT/P listing? • Removes from proposed § 1271.25(a)(6) the requirement that each foreign HCT/P establishment designate only one United States agent. • Removes a reference to Form FDA 3356 in proposed § 1271.25(c)(4). • Revises proposed § 1271.25(d) to clarify that it pertains to HCT/Ps regulated under BLAs and to state that establishment registration and listing information for such products must be submitted in accordance with the electronic submission requirements of part 207, subpart E.

This final rule does not include the proposed amendments to §§ 330.1, 610.60, and 610.61, all of which dealt with NDCs on labels. This final rule also does not include the proposed minor amendment to § 1271.37 (regarding public disclosure of HCT/P establishment registration and listing information) in light of the technical amendments adopted on April 3, 2015 (80 FR 18087).

Some changes from the proposed rule not addressed in section III (Comments on the Proposed Rule) are addressed in the following paragraphs.

Active pharmaceutical ingredient: To prevent confusion, we proposed to replace the term "bulk drug substance" with the more descriptive term "active pharmaceutical ingredient." This change is retained in the final rule. Sections 503A(b)(1)(A) and 503B(a)(2) of the FD&C Act (21 U.S.C. 353a(b)(1)(A) and 353b(a)(2)), however, refer specifically to the definition of "bulk drug substance" within part 207. To ensure conformity with the FD&C Act, both "bulk drug substance" and "active pharmaceutical ingredient" are defined in § 207.1 of the final rule. As intended by the proposed rule, "active pharmaceutical ingredient" will have the same meaning as "bulk drug substance."

Salvage: In this final rule, the term "salvage" is defined to mean the act of segregating out those finished drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products to the marketplace and includes applying manufacturing controls such as those required by current good manufacturing practice in parts 210 and 211 (21 CFR parts 210 and 211). Substantively, this matches the definition of "drug product salvaging" included in the proposed rule, but the words have been rearranged for greater clarity. This final rule also includes a definition for the term "salvager."

Establishment registration number and Unique Facility Identifier: We proposed to define the term "establishment registration number" in § 207.1 to mean "the number assigned by FDA to the establishment during the establishment registration process required in this part." The final rule changes the definition of "establishment registration number" slightly to state that the number is assigned "after" the registration process, rather than "during."

The establishment registration number identifies establishments for inspection by FDA. Historically, an establishment registration number is assigned to each establishment of each manufacturer, repacker, relabeler, or salvager after the initial registration, when such activities begin. In the preamble to the proposed rule, we explained that "[c]urrently, the FDA Establishment Identifier (FEI) will be the number we assign as the establishment registration number. In the future, however, we may use a different number as the establishment registration number" (71 FR 51276 at 51288).

After the proposed rule was published, FDASIA amended section 510 of the FD&C Act to require persons subject to the drug establishment registration requirement to submit a UFI. In the electronic registration and listing guidance, FDA stated that it intended to use the DUNS number, assigned and managed by Dun & Bradstreet, as a registration number. To implement the UFI provision of FDASIA, FDA also issued guidance in 2014 that specified the DUNS number as the preferred UFI.[1]

Under the final rule, the establishment registration number and the UFI are two distinct numbers. For now, FDA will continue to assign an FEI as the establishment registration number after an establishment is registered for the first time. The final rule requires registrants to submit the establishment registration number (currently the FEI), "if previously assigned by FDA," under § 207.25. Someone registering an establishment for the first time is not expected to have a registration number for the establishment. Such a registrant is required to submit its registration number at the time of the first annual review and update of registration information under § 207.29(b) of this final rule and is encouraged to submit the registration number sooner, as soon as it is received from FDA. The establishment registration number does not need to be submitted at the time of each annual registration update under § 207.29 unless the establishment registration number has changed. Likewise, the UFI, currently specified as the DUNS number, must be submitted when registering an establishment for the first time under § 207.25. The UFI does not need to be submitted at the time of each annual registration update under § 207.29 unless the UFI has changed.

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[1] See the guidance for industry "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration," November 2014, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs).

Bar code label requirements (§ 201.25): As explained in section III, this final rule does not include two proposed amendments to § 201.25. It does, however, include a minor new amendment to § 201.25. To accommodate the possibility of alternatively formatted NDCs in bar codes, § 201.25 is amended in this final rule to allow FDA's Center Directors to approve additional standards or formats for bar codes.

Submission of approved U.S. application number instead of inactive ingredients (§ 207.33(c)(2)): Information registrants would have submitted under § 207.33(c) of the proposed rule to obtain an NDC has been shifted to drug listing information required under § 207.49 of this final rule. Under § 207.49(a)(5) of this final rule, a registrant must provide the name of each inactive ingredient in a listed drug it manufactures. The option to submit an approved application number instead of a list of inactive ingredients is not retained in the final rule because FDA is not currently able to pull inactive ingredient information from approved applications to our drug listing systems.

III. Comments on the Proposed Rule

In the **Federal Register** of October 31, 2006 (71 FR 63726), FDA announced an extension of the comment period for this rulemaking and a public meeting to discuss the proposed changes to the NDC system presented in the proposed rule. The public meeting was held on December 11, 2006. In the **Federal Register** of February 8, 2007 (72 FR 5944), FDA announced a reopening of the comment period because technical problems prevented some persons from submitting comments electronically on the last day of the previous comment period. The Agency received numerous comments, including oral presentations made at the December 2006 public meeting and approximately 200 written comments placed in the docket. Comments were received from prescription and nonprescription drug manufacturers and related companies, trade associations representing drug manufacturers and other interested parties, academic institutions, and professional associations.

The docket for this rulemaking, Docket No. FDA–2005–N–0464, was also used to collect comments on FDA's draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing" (74 FR 26248). In this final rule, we are responding to comments that pertain to the rulemaking, *i.e.*, comments that relate to the changes in regulations proposed on August 29, 2006.

To make it easier to identify comments and our responses, the word "Comment," in parentheses, appears before the comment's description, and the word "Response," in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

A. Labeling (§§ 201.2 and 201.25)

The proposed rule included amendments to § 201.2 that would have required drugs subject to the listing requirement of part 207 to have labels that bear the appropriate NDC in human-readable form. As discussed in this document, this final rule does not include the proposed amendments that would have made human-readable NDCs mandatory on drug labels.

Section 201.2 currently states that NDCs are "requested but not required" to appear on all drug labels. Section 201.25 currently requires bar codes on prescription human drug labels with certain exceptions and on certain nonprescription human drug labels. Section 201.25(c) currently specifies that each bar code must contain, at a minimum, the appropriate NDC.

Sections 201.2 and 201.25 currently do not specify which NDC should appear on labels and in bar codes apart from referring to it as "the appropriate" NDC (§ 201.25(c)). This implies that the NDC appearing on a drug's label match an NDC under which the drug is appropriately listed under part 207.

1. NDC Numbers (§ 201.2)

Pharmacists and health care providers use NDCs currently appearing on drug labels in a variety of ways, including to help prevent medication errors and to process prescription drug reimbursement claims. We believe there is currently a high level of cooperation with FDA's request in § 201.2 that NDCs appear in human-readable form on labels, as drug manufacturers recognize the importance of this information.

In addition to making human-readable NDCs on drug labels mandatory, the proposed rule would have specified which NDC must appear on labels. Specifically, proposed § 201.2(b) sought to define the appropriate NDC for this purpose as being that of the last manufacturer, repacker, relabeler, or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer.

(Comment 1) Several comments recognized the importance of having NDCs in human-readable form on labels, but many objected to FDA's proposed provisions defining the appropriate NDC in proposed § 201.2(b). In particular, certain repackers objected to the proposed requirement that a repacker's NDC, rather than that of the original manufacturer, appear on the labels of repackaged drug products.

(Response) This final rule does not include the proposed amendments to § 201.2 that would have made human-readable NDCs mandatory on drug labels. It includes only a conforming amendment to that section (replacing the reference to § 207.3(b)(3) with an updated reference to new § 207.1).

The Drug Quality and Security Act (DQSA) (Pub. L. 113–54) of 2013 includes as Title II the Drug Supply Chain Security Act (DSCSA). The DSCSA requires drug manufacturers and repackagers (as defined in sections 581(10) and 581(16) of the FD&C Act, respectively) to affix or imprint a *product identifier* on packages for certain prescription drugs for human use. Under section 581(14) of the FD&C Act, a "product identifier" is a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, the "standardized numerical identifier," lot number, and expiration date of the product. The NDC is one component of the standardized numerical identifier. FDA has determined that because the DSCSA requires the inclusion of NDCs on certain prescription drug labels (as part of a product identifier), it is unnecessary to include the proposed amendments to § 201.2 in this final rule.

Our determination that the proposed amendments to § 201.2 should not be finalized renders moot many comments concerning identification of the appropriate NDC for labeling purposes, along with placement and formatting issues. Therefore, we do not respond to those comments.

The DSCSA does not require manufacturers or repackagers to affix or imprint product identifiers on nonprescription human drug products or on animal drugs. Therefore, we will maintain the status quo for those drug products, meaning FDA will continue to request that NDCs in human-readable form appear on all drug labels and in all drug labeling, as indicated in § 201.2. We may revisit a regulatory requirement that human-readable NDCs appear on the labels of nonprescription human drug products and animal drugs in the future.

2. Bar Code Label Requirements (§ 201.25)

Section 201.25 currently requires that a human drug product's NDC be included in its bar code. We proposed to amend § 201.25 in two minor ways: (1) To add a cross-reference to proposed new § 201.2(b), which would have described the "appropriate NDC" for labeling purposes and (2) to add new § 201.25(e) stating that a bar code may be displayed on certain drug product labels voluntarily but only if it meets the requirements of § 201.25(c). Neither proposed amendment to § 201.25 is retained in the final rule.

(Comment 2) The Animal Health Institute expressed concern that proposed § 201.25(e) would unreasonably burden its members who, although they are not currently required by § 201.25 to place bar codes on animal drug labels (because it applies to human drugs), may do so for logistical reasons. They asked that the animal health industry be exempt from the requirement to include an NDC in any bar codes appearing on animal drug labels. Similar comments were received from manufacturers of allergenic extracts. Allergenic extracts are currently exempt from the bar code requirement (see § 201.25(b)(1)(i)(B)). Commenters explained that manufacturers of allergenic extracts may place bar codes on their labels for inventory, warehousing, and other logistical purposes. They objected to proposed § 201.25(e) to the extent that it would require such bar codes to include NDCs.

(Response) FDA has not retained proposed § 201.25(e) in this final rule.

(Comment 3) A group of comments asserted that 11-digit NDCs cannot be encoded into a bar code that meets European Article Number/Uniform Code Council or Health Industry Business Communications Council standards, as required by current § 201.25(c). Another comment urged FDA to remove the NDC from bar codes.

(Response) This final rule acknowledges that 10-digit NDCs will be exhausted at some point in the future as a mathematical inevitability. As discussed in our response to Comment 52, this final rule reduces the number of occasions when a change to a drug requires a new NDC under § 207.35. This final rule also amends § 201.25 to allow FDA's Center Directors to approve additional bar code standards and formats.

As discussed in response to Comment 1, the DSCSA requires the inclusion of product identifiers on prescription human drug labels and defines "product identifier" to mean a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier the standardized numerical identifier, lot number, and expiration date of the product. The standardized numerical identifier, a component of the product identifier, is comprised of the NDC and a serial number.

FDA continues to recognize the importance of NDCs on drug labels in both machine-readable and human-readable form. We remind manufacturers of the current requirement in § 201.25 that bar codes on human drug labels include the appropriate NDC, and we encourage manufacturers to continue to provide the NDC in human-readable form on drug labels where not required by the DSCSA.

B. General Information (Part 207, Subpart A)

1. What definitions and interpretations of terms apply to this part? (§ 207.1)

The proposed rule included a set of terms and definitions in §§ 207.1, 607.3, and 1271.3. These definitions are retained in the final rule with several modifications. Additionally, the final rule includes definitions for the terms "finished drug product," "unfinished drug product," "bulk drug substance," "outsourcing facility," "private label distribution," and "registrant" in § 207.1 and a definition of "foreign" in § 607.3.

a. Commercial distribution. In the proposed rule, the definition of "commercial distribution" excluded "the internal or interplant transfer of an active pharmaceutical ingredient between registered establishments within the same parent, subsidiary, and/or affiliate company."

In the final rule, the definition does not include the phrase "an active pharmaceutical ingredient" so that internal or interplant transfers between such registered establishments are not treated as commercial distribution under part 207, whether the transfer involves active pharmaceutical ingredients, other unfinished drug products, or finished drug products.

(Comment 4) A comment suggested that the definition of "commercial distribution" be revised to exclude transfers between a registered establishment and a marketing authorization holder when the two are in a contractual relationship. Otherwise, this comment argued, products marketed by private label distributors who employ contract manufacturers are held to a higher burden of documentation than products manufactured and distributed by the same entity.

(Response) We disagree with the suggestion that a transfer of drugs from a contract manufacturer to another contracting party should not qualify as commercial distribution. Such an exemption would interfere with FDA's ability to track drugs and establishments for inspection. However, by revising the definition of "commercial distribution" to exclude internal or interplant transfers of drugs, including active pharmaceutical ingredients, other unfinished drugs, and finished drug products, between registered establishments under common ownership and control, we have reduced the drug listing burden generally. This exclusion accommodates the common practices of specialized manufacturing at different registered establishments under common ownership and control. This practice often results in multiple internal and interplant transfers of these materials prior to marketing, which we do not consider commercial distribution for registration and listing purposes.

b. Content of labeling. The proposed rule included a multipart definition for the term "content of labeling" with separate provisions applicable to:

- Human prescription drugs that the manufacturer regards as subject to section 505 of the FD&C Act or section 351 of the PHS Act, *i.e.*, subject to premarket approval from FDA;
- Human prescription drugs that the manufacturer regards as not subject to section 505 of the FD&C Act or section 351 of the PHS Act;
- Human nonprescription drugs; and
- Animal drugs.

The term "content of labeling" was used in the proposed rule to describe some, but not all, labeling that must be submitted with drug listing information. For example, proposed § 207.49(g)(2)(i) stated that listing information for certain human over-the-counter (OTC) drugs must include "all current labeling . . . including the content of labeling." Content of labeling is defined in a very similar way in the final rule with deletion of the phrase "that the manufacturer regards as" and the addition of a reference to the labeling requirements for veterinary drugs in 21 CFR part 201.

We removed the language "that the manufacturer regards as subject to section 505 [or 512] of the FD&C Act or section 351 of the PHS Act" and added in its place language that refers to drugs as being either subject or not subject to those provisions. We made this change after determining that the manner in which content of labeling is defined should not depend on a manufacturer's subjective understanding or intent with respect to sections 505 or 512 of the FD&C Act or section 351 of the PHS Act.

The revised definition includes, among others, the category "human prescription drugs that are not subject to section 505 of the FD&C Act or section 351 of the PHS Act." We have retained this construction even though FDA considers it unlikely that any currently marketed human prescription drug product is grandfathered or is otherwise not a new drug subject to those provisions. However, the Agency recognizes that the existence of such drugs is at least theoretically possible. No part of this final rule is a finding as to the legal status of any particular drug product.

Regarding animal drugs, in part four of the definition of "content of labeling" and in other places throughout this final rule, the phrase "subject to section 512" means, for purposes of this final rule, drugs meeting the definition of "new animal drug" as that term is defined in section 201(v) of the FD&C Act, and which therefore are subject to some or all of the provisions relating to new animal drugs found in section 512 of the FD&C Act. This term includes not only new animal drugs that are approved under section 512 but also new animal drugs that are conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc) or indexed under section 572 of the FD&C Act (21 U.S.C. 360ccc–1). The phrase "all other animal drugs" as used in provisions of this final rule at §§ 207.49(a)(15)(iii) and 207.53(d)(3) describing the labeling registrants must provide as part of the listing for an animal drug, refers to animal drugs that do not meet the definition of new animal drug found in section 201(v) of the FD&C Act (*e.g.,* grandfathered animal drugs). Although the Agency recognizes that the existence of such animal drugs is theoretically possible, we believe it is unlikely that any currently marketed animal drug product is grandfathered or otherwise not a "new animal drug" subject to section 512 of the FD&C Act.

(Comment 5) Commenters asked FDA to clarify how content of labeling differs from package inserts and final printed labeling.

(Response) A prescription human drug product's FDA-approved labeling is sometimes referred to as a "package insert" or as "professional labeling." In defining the term "content of labeling," for human drugs, we use the phrase "prescription drug labeling" (instead of "package insert" or "professional labeling") to mean FDA-approved labeling for prescription drug products described in §§ 201.56, 201.57, and 201.80. For human prescription drugs that are subject to section 505 of the FD&C Act or section 351 of the PHS Act, content of labeling is defined as the content of the prescription drug labeling. For human OTC drugs, content of labeling is not defined in these terms; it includes "all text, tables, and figures including the drug facts labeling required by § 201.66." For animal drugs, "content of labeling" is defined to mean labeling that accompanies the drug that is necessary to enable safe and proper administration of the drug. This would generally include package inserts and final printed labeling. Sections 207.49 and 207.53 require submission of labeling with drug listing information. In most cases, all current labeling must be submitted, including the content of labeling.

(Comment 6) A comment stated that FDA should more clearly delineate between the terms "label" and "labeling" throughout the rulemaking, rather than using the term "labeling" to refer to both. This comment pointed out that the proposed rule's definition of content of labeling for human OTC drugs referred to "labeling required by § 201.66," but § 201.66 pertains to information appearing on the "outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper" (§ 201.66(c)).

(Response) We have clarified in § 207.1(a) of the final rule that the definitions and interpretations of terms in sections 201 and 510 of the FD&C Act apply to the terms used in part 207 unless otherwise defined. Accordingly, the term "label" means a display of written, printed, or graphic matter upon the immediate container of any article consistent with section 201(k) of the FD&C Act. The term "labeling" more broadly includes both immediate container labels and other written, printed, or graphic matter accompanying such article consistent with section 201(m) of the FD&C Act. When we intend to refer only to immediate container or package labels, we use the term "label." More often, we use the broader term "labeling" in this final rule to encompass both immediate container labels and/or other written, printed, or graphic matter accompanying the drug, as the labeling definition in section 201(m) of the FD&C Act has been interpreted. The term "content of labeling" is defined slightly differently for human prescription drugs, human OTC drugs, and animal drugs, and the term is intended to encompass both labels and labeling.

The proposed rule (proposed § 207.1) referred only to definitions in section 510 of the FD&C Act, and the preamble to the proposed rule suggested that reference to the definitions in section 201 of the FD&C Act was intentionally omitted (71 FR 51276 at 51285). Consistent with 21 CFR 1.1(b), this final rule clarifies that the definitions in section 201 of the FD&C Act apply to the terms used in part 207.

c. Establishment. We proposed to define "establishment" in § 207.1 as "a place of business under one management at one geographic location." The definition in proposed § 207.1 also stated "one geographic location may include separate buildings within the same city if their activities are closely related to the same business enterprise and are under the supervision of the same local management."

Rather than adopt this proposed definition, the final rule retains the definition of the term "establishment" that has appeared in the part 207 regulations since 1980. This definition states that an establishment is "at one general physical location."

(Comment 7) One comment suggested that the phrase "within the same city" used in the proposed definition of "establishment" was too specific. This comment argued that a manufacturing facility located in a city with a warehouse located just outside that city should together be treated as a single establishment for registration purposes.

(Response) In reviewing this comment and considering it in light of the longstanding definition of "establishment" and the objectives behind the establishment registration requirement, we determined that the existing definition in part 207 is clearer and better serves our objectives than would the proposed amended definition. The longstanding language, "one general physical location," generally restricts a single establishment to one street address or one or more contiguous plots of land. We do not agree with the comment that a second facility located in a different city should be covered by the first facility's establishment registration.

We note, however, that a facility operated only as a warehouse may not require registration. Section 510 of the FD&C Act and § 207.17 of this final rule require registration of establishments where drugs are manufactured, repacked, relabeled, or salvaged. A facility at which drugs are merely stored may not require registration under this final rule, unless the facility includes, for example, controlled storage for stability testing as an element of good manufacturing practices. Other Federal and State requirements may apply to such facilities.

Likewise, the corporate headquarters of a drug establishment should not register under this rule if drugs are not manufactured, repacked, relabeled, or salvaged at that location.

d. Foreign. We proposed to use the term "foreign" to refer to a manufacturer, repacker, relabeler, drug product salvager, or private label distributor who is located in a foreign country and who manufactures, repacks, relabels, salvages, or distributes a drug that is imported or offered for import into the United States. When used to modify "establishment," we proposed to use "foreign" to refer to an establishment that is located in a foreign country and is the site where a drug that is imported or offered for import into the United States was manufactured, repacked, relabeled, salvaged or distributed.

We have omitted the words "or distributed" from this definition because only establishments at which drugs are manufactured, repacked, relabeled, or salvaged are required to be registered.

(Comment 8) One comment urged us to revise the definition of "foreign" to mean "located in a foreign country" while stating in § 207.9 that part 207 applies to foreign entities who import or offer for import products into the United States.

(Response) We do not agree that the proposed rule was confusing or difficult to understand in this respect and have decided against making this change.

e. Importer. Section 207.25 of this final rule and section 510(i) of the FD&C Act require foreign establishments, when registering, to provide names and contact information for each importer in the United States of drugs manufactured, repacked, relabeled, or salvaged at the establishment that is known to the establishment. We proposed to define "importer" to mean, in part, "a company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States." In proposing this language, we recognized that a foreign establishment may have more than one importer, and we proposed to include in this term any owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's drug that is imported into the United States.

(Comment 9) Some comments stated that our proposed definition of the term "importer" was too broad and would increase the burden on manufacturers to provide unnecessary information concerning a wide variety of entities that are not responsible for the drug. One comment noted that the inclusion of downstream recipients in our definition of "importer" would impose a significant reporting burden on foreign establishments that is not required of domestic establishments.

(Response) We agree that we should clarify and narrow the proposed definition of "importer." As proposed, the definition included every U.S. recipient of a foreign-produced drug, excepting only the final consumer or patient. Of this large group, foreign establishments would be required to identify in their establishment registration submissions only those importers that are known to the establishment. To make this information element more useful to FDA and to reduce the burden on registered establishments, we have determined that in this context the term "importer" should include a U.S. owner, consignee, or recipient *at the time of the drug's entry into the United States* and should not include additional subsequent owners, consignees, or recipients of the drug. We have revised the definition of importer in § 207.1 of the final rule accordingly.

(Comment 10) One comment recommended that we change "company or individual" to "person," in the rule's definition of "importer," consistent with the definition of the term "person" in section 201(e) of the FD&C Act.

(Response) We agree that the term "person," as defined in the FD&C Act, is an improvement over "company or individual" in this definition. We have made this change in §§ 207.1 and 607.3 of the final rule, and as discussed in our response to comment 6, we have also added a statement in §§ 207.1(a) and 607.3(a) that the definitions and interpretations of terms in sections 201 and 510 of the FD&C Act apply if not otherwise defined.

f. Person who imports or offers for import. Section 207.25 of this final rule and section 510(i) of the FD&C Act also require foreign establishments, when registering, to supply names and contact information for each person who imports or offers for import drugs manufactured, repacked, relabeled, or salvaged at the establishment. The proposed rule's definition of "person who imports or offers for import" included "an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its drug into the United States." We invited comments on the use and interpretation of the term "facilitate."

(Comment 11) Some comments expressed concern regarding the potential breadth of this definition, noting in particular that the word "facilitate" could, in theory, encompass entities such as foreign insurance adjusters, underwriters, and international banks. Commenters pointed out the significant burden associated with the identification of such entities in foreign establishment registrations and updates to registrations, noting that international supply chains and business relationships are not static. One comment urged FDA to exclude customs brokers from the rule's definition of "person who imports or offers for import." Another comment encouraged FDA to exclude middlemen from this definition, as their identities would change frequently.

(Response) Although we did not intend for the word "facilitate" to be read as broadly as some comments suggested, FDA agrees that the definition of "person who imports or offers for import" should be made more precise, narrow, and useful.

We note, as a matter of clarification, that in section 510(i) of the FD&C Act and in § 207.25 of the final rule, the requirement that foreign establishments identify each person who imports or offers for import is not said to be limited to persons known to the establishment (unlike the requirement that they identify "importers"). The preamble to the proposed rule included statements that were inconsistent with the FD&C Act in this regard, suggesting that foreign establishments would be required to report the name of each person *known to the establishment* who imports or offers for import its drug(s) into the United States. See, *e.g.*, 71 FR 51276 at 51289. In fact, the proposed rule (proposed § 207.25), the final rule, and the FD&C Act all require foreign establishments to report, when registering, the name of each person who imports or offers for import its drug(s) into the United States without regard to whether such persons are known to the establishment. Therefore, it is important that we define "person who imports or offers for import" in a way that is practical, useful, and consistent with this understanding.

Our intention in defining this term is to include foreign persons who are primarily responsible for sending a drug to the United States. Foreign establishments are reasonably expected to know the identities of such persons. In many cases, the establishment itself will be a person who imports or offers for import its drugs into the United States. In other cases, it will be a person the foreign establishment engages to send one or more drugs to the United States. It will generally be the foreign person who owns the drug and sells or enters into a contractual obligation to supply the drug to a person in the United States.

In light of the comments received and FDA's objectives, the final rule defines "person who imports or offers for import" to mean the owner or exporter of a drug who consigns and ships a drug from a foreign country to the United States. This definition includes persons who send a drug to the United States by international mail or other private delivery service, but does not include carriers who merely transport the drug. This definition is not intended to include persons operating merely as customs brokers.

g. Manufacture, manufacturer. The definitions of "manufacture" and "manufacturer" in § 207.1 of this final rule include minor editorial revisions for clarity and new references to animal feed bearing or containing a new animal drug.

(Comment 12) Some comments stated that the definition of "manufacturer" should specify that it applies only to entities manufacturing drugs for commercial distribution.

(Response) We disagree with the recommendation that the definition of "manufacturer" be limited to drugs manufactured "for commercial distribution." The underlying statutory provisions require registration of establishments where drugs are manufactured, without regard to commercial distribution (section 510(c) of the FD&C Act), but require listing of drugs that are manufactured for commercial distribution (section 510(j) of the FD&C Act). Accordingly, under § 207.17 of this final rule, each domestic establishment where a drug is manufactured (or repacked, relabeled, or salvaged) must be registered unless exempt from registration under section 510(g) of the FD&C Act or under § 207.13, regardless of whether the drug is commercially distributed. The drug listing obligation, as described in § 207.41, applies to drugs that are manufactured, repacked, relabeled, or salvaged for commercial distribution. (See separate definition of "commercial distribution.")

(Comment 13) One comment asked that drug sponsors be included in the definition of manufacturer. Other comments suggested that FDA add "product formulator" to the definition of "manufacturer" or provide definitions for terms such as "drug sponsor." These comments pointed out that the holder of an approved application, such as an NDA, or the formulator of a nonprescription monograph product may use a contract manufacturer to produce the product for distribution under the name of the application holder or the product formulator. Some comments recommended that the final rule treat such application holders or product formulators as manufacturers so they would register their establishments and list such products and that it exempt contract manufacturers from the drug listing requirement.

(Response) We decline to add the application holder or "product formulator" concepts to the definition of "manufacturer." Under section 510(c) of the FD&C Act, the obligation to register drug establishments rests on owners or operators of establishments engaged in the manufacture (including repacking, relabeling, and salvaging) of drugs, and the listing obligation applies to "every person who registers." FDA recognizes that this language could be read broadly to encompass entities that develop or formulate drug products without performing manufacturing operations. However, considering the objectives behind drug registration and listing, we are currently interested in the registration of establishments where manufacturing operations (including repacking, relabeling, and salvaging) take place and the listing of drugs handled at those establishments.

We recognize, however, that an application holder or a product formulator using a contract manufacturer to manufacture a drug may wish to submit drug listing information for that product directly to FDA. Although the actual manufacturer of the drug has the legal obligation to list it, FDA would accept listing information for the drug submitted by its formulator or any other person acting as an authorized agent for the manufacturer. When we use the term "authorized agent" in this final rule, we mean a person who is authorized to act on behalf of another. The term "authorized agent" should not be confused with the United States agent referred to in § 207.69(b).

(Comment 14) Several comments asked for clarification on how the terms "manufacture," "repackage," "relabel" and "private label distributor" would apply to the medical gas industry and pointed out that certain medical gas operations, such as the transfilling of gas from one container to another, have long been treated as drug manufacturing by FDA but, under the proposed rule, would seem to qualify as "repacking." These comments asked FDA to classify medical gas refillers as "manufacturers" rather than "repackers" in the final rule.

(Response) FDA agrees that these important points require clarification. Nothing in this final rule is intended to alter the definitions applicable to FDA's regulations governing current good manufacturing practices for drug products, parts 210 and 211. Therefore, the definition of "manufacture, processing, packing, or holding of a drug product" currently appearing in § 210.3(b)(12) will continue to apply to medical gases as that definition has always applied.

For purposes of part 207, we will interpret the definition of "manufacture" in § 207.1 as including the initial manufacturing process that produces or purifies a medical gas, whether by air separation, chemical reaction, or other process. Additionally, the mixing of two or more medical gases to produce a combination would also qualify as "manufacture" under § 207.1. The impact of this interpretation is that a person who thus qualifies as a manufacturer of a medical gas will be required to submit the drug listing information required under § 207.49 of this final rule ("What listing information must a registrant submit for a drug it manufactures?") in addition to registering the establishment(s) at which manufacturing is conducted.

All subsequent transfillings of a medical gas from one container to another (*i.e.,* from tanker trucks into standing tanks and from standing tanks into smaller containers, etc.) would fall within the definition of "repack or repackage" in § 207.1 of this final rule. The impact of this interpretation is that a person who thus qualifies as a repacker of a medical gas will be required to submit the drug listing information required under § 207.53 of this final rule ("What information must a registrant submit for a drug that it repacks or relabels?") in addition to registering the establishment(s) at which repackaging is conducted. Comments opposing this classification expressed concern that under the proposed rule, repackers would be required to identify the NDC assigned to a drug immediately before it is received by the repacker as information that must be submitted to obtain an NDC for a repackaged drug under proposed § 207.33(d)(1)(ii). See our response to Comment 73 regarding an exemption for medical gases from the requirement that registrants submit such source NDCs for drugs they repackage or relabel.

The definition of "relabel" in § 207.1 of this final rule applies to medical gases. It refers to changing or altering the existing label on a drug or drug package, without repacking the drug or drug package. A person who places a label on a repackaged drug (*e.g.,* a medical gas recently filled into a canister) for the first time qualifies as a "repackager" as that term is defined in this final rule.

The term "private label distributor" is defined in § 207.1 of this final rule to mean, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed. This definition applies equally to private label distributors of medical gases and other drugs. A medical gas transfiller is a repackager, and not a private label distributor, under this final rule. As discussed in our response to comment 16, private label distributors do not—by reason of their status as private label distributors—have an obligation to register establishments or list drugs. They must have labeler codes, obtained under new § 207.33(c), and they may submit drug listing information or establishment registration information if acting as the authorized agent of a registrant on whose behalf the information is submitted.

h. Material change. In the proposed rule, "material change" was defined as any change in any drug listing information, excluding labeling changes in arrangement or printing or labeling changes of an editorial nature. This definition is retained in the final rule with minor revisions to clarify that material change also does not include changes in the format of labeling, or the inclusion of a bar code or the initial inclusion of an NDC on a label.

(Comment 15) One comment asked FDA to clarify the types of labeling changes that would qualify as a material change and, hence, require reporting as an update to drug listing information under § 207.57. This comment specifically suggested examples of labeling changes that would qualify as significant changes in the labeling of a prescription drug product or significant changes in the label or package insert of an OTC drug product.

(Response) In referring to "significant" labeling changes, this comment seems to relate to the longstanding definition of "material change" in § 207.3(a)(3), prior to this final rule, which encompassed labeling changes described as "significant." Today's final rule revises that definition so that material change includes any labeling change other than changes in the format of labeling, changes of an editorial nature, inclusion of a bar code, or initial inclusion of an NDC. In this context, changes of an editorial nature would not include any changes that add or revise meaning.

Thus, the new definition of "material change" adopted as part of this final rule is broader than the previous definition and is not limited to "significant" changes. The definition includes—with very few exceptions—any change in previously reported drug listing information. FDA intends to rely primarily on new § 207.57 to maintain an up-to-date database of current drug labeling. Registrants should submit current labeling (and a resubmission of all listing information) each time they submit a drug listing update to report changed information under § 207.57.

i. Private label distributor. We proposed to define "private label distributor" to mean a person who owns or operates an establishment that commercially distributes, under its own label or trade name, any drug manufactured, repacked, relabeled, or salvaged by a registered establishment. In the preamble to the proposed rule we explained that the private label distributor does not engage in any activities performed by a manufacturer, repacker, relabeler, or salvager for the drug it distributes (71 FR 51276 at 51290).

In the final rule, private label distributor is defined to mean, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed. We have also defined "private label distribution" in this final rule to mean commercial distribution of a drug under the label or trade name of a person who did not manufacture, repack, relabel, or salvage that drug.

(Comment 16) Some comments requested clarification regarding the distinction between private label distributors, manufacturers, and wholesale distributors. Others urged FDA to allow private label distributors to list the drugs they distribute. One comment requested clarification regarding the responsibilities of private label distributors under part 207.

(Response) We agree that more clarity is needed regarding these terms and the registration and listing obligations associated with private label distribution of drug products. We have eliminated the mention of establishment ownership in the proposed rule's definition of "private label distributor" because private label distributors do not necessarily own establishments that require registration under section 510 of the FD&C Act. We have also clarified that an entity may act as a private label distributor with respect to a particular drug. For example, if a drug manufacturer distributes, under its own name or trade name, a drug manufactured entirely by a contract manufacturer, it is acting as a private label distributor with respect to that drug. The difference between private label distributors and wholesale distributors or others involved in drug distribution is that a private label distributor's name, trade name, or label appears on the product. A common example of private label distribution is the sale of aspirin under a retail pharmacy's brand name when the retail pharmacy did not manufacture the product. As defined in this final rule, private label distribution encompasses the use of any brand name or business name on a drug product where the named business or the owner of the brand name did not manufacture the drug. Thus, as we are defining the term in part 207, a private label distributor may, but does not necessarily, operate retail stores or play a role in the physical distribution of the drug product. Even without using a brand name, if an entity is identified as the distributor or marketer of a drug under § 201.1 of the drug labeling regulations, without having manufactured the drug, that person will qualify as a private label distributor as the term is defined in this final rule.

Under this final rule, private label distributors do not have registration or listing obligations with respect to drugs for which they merely act as private label distributors. Only manufacturers, repackers, relabelers, and salvagers have an obligation to register and list. Private label distributors are subject to this final rule only in that they must apply for an NDC labeler code as described in § 207.33(c) and update the information submitted under that section when the information changes. Private label distributors are in the best position to obtain their own labeler codes and update information associated with those codes, thereby preventing potential submissions of inconsistent or inaccurate information by multiple contract manufacturers.

A person who is a private label distributor with respect to a particular drug does not for that reason incur an establishment registration or listing obligation. The FD&C Act and the regulations in part 207 both place the registration and listing obligation on persons who manufacture, repack, relabel, or salvage drugs. The registration and listing obligation thus rests with the actual manufacturer, repacker, relabeler, or salvager whether or not a product is intended for private label distribution. For this reason, the final rule does not include provisions regarding establishment registrations or drug listings submitted by private label distributors.

We recognize, however, that some private label distributors are in a position to supply listing information, including NDCs, for drugs distributed under their names and may prefer to do so. FDA will accept registration and listing information submitted by any authorized agent acting on behalf of a manufacturer, repacker, relabeler, or salvager, and this includes a private label distributor authorized by a manufacturer, repacker, relabeler, or salvager, to submit drug listing information on its behalf. In these cases, the manufacturer, repacker, relabeler, or salvager remains responsible for compliance with all registration and listing requirements and the accuracy of the information submitted by its agent.

A person who acts merely as a wholesale distributor of a drug product (i.e, a person who did not manufacture, repack, relabel, or salvage the drug product and whose name, trade name, or label does not appear on the drug product) does not incur obligations under this rule.

j. Relabel, relabeler, repack, repacker. We proposed to define "relabel" to mean changing the label or labels on a drug or drug package, or adding to the labeling for a drug or drug package, without repacking the drug or drug package. We also proposed to define "relabeler" to mean a person who owns or operates an establishment that relabels a drug.

We proposed to define "repack" to mean repack or repackage or otherwise change the container or wrapper of a drug or drug package. Similarly, we proposed to define "repacker" to mean a person who owns or operates an establishment that repacks a drug or drug package.

In the final rule, these definitions are clarified and revised in response to comments.

(Comment 17) Some comments noted that the definition of relabel could include wholesale drug distributors who add information to outer container labels for purposes of delivery to a customer, customer identification, inventory management, special handling instructions, or to aid in compliance with Federal and State pedigree requirements. Commenters urged us not to require establishments (*e.g.,* distribution facilities) where such relabeling occurs to register and list.

(Response) We agree generally with these comments and have revised the definition of "relabel" in the final rule to exclude the addition or modification of information affixed solely for purposes of delivery to a customer, customer identification, or inventory management. However, we did not exclude the addition of special handling instructions from the definition of "relabel," as recommended in these comments. Such an exclusion might be misinterpreted as accommodating revised storage instructions in drug labeling. However, FDA would not object to the addition of storage information to an outer label if such information is not inconsistent in any way with storage instructions appearing elsewhere in the drug's labeling. In that case, FDA would not regard the addition of such storage information to an outer container label as relabeling that would subject a person to registration and listing.

k. Representative sampling of advertisements and *Representative sampling of any other labeling.* The definitions of these terms included in the proposed rule appear in this final rule with one minor revision.

(Comment 18) The preamble to the proposed rule included a brief discussion of these definitions. That discussion pointed out a confusing aspect of the previous definitions of these terms and the previous definition of the term "advertising and labeling" in part 207. See 71 FR 51276 at 51291. One comment argued that there was no conflict in these definitions and urged FDA to retain our previous definitions of "representative sampling of advertisements" and "representative sampling of any other labeling." This comment pointed out that the examples given in those previous definitions were helpful.

(Response) We disagree with this comment. The revised definitions are intended to eliminate some confusion associated with the previous definitions as explained in the preamble to the proposed rule. The examples appearing in the previous definitions read as follows: "If more than one medical journal advertisement is used but the promotional content is essentially identical, only one need be submitted" and "if more than one brochure is used but the promotional content is essentially identical, only one need be submitted." The quoted language served as common sense guidance regarding the application of the definitions without being a central part of the definitions. Although omitting that language from the definitions included in the proposed rule and this final rule, FDA is not disavowing the examples or suggesting that registrants should take a different approach.

2. Who does this part cover? (§ 207.9)

The Agency proposed new § 207.9 to clarify the types of businesses that are subject to drug establishment registration and listing under part 207. Section 207.9 is retained in this final rule with certain revisions and clarifications.

Section 207.9(a)(3) of this final rule clarifies that private label distributors are subject to part 207. As discussed previously in this document, private label distributors do not have an obligation to register an establishment or list any drugs arising from their activities as private label distributors. They are, however, expected to obtain NDC labeler codes under § 207.33(c) of this final rule and update the information reported to FDA under § 207.33(c) as required by § 207.33(c)(2).

Section 207.9(a)(4) of this final rule is revised to state more clearly its applicability to establishments engaged in the manufacture, repacking, relabeling, or salvaging of drugs regulated under a BLA. These establishments are subject to part 207 unless they are required to register and list under part 607 (ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS).

Section 207.9(a)(5) of this final rule is revised to state that HCT/Ps, as defined in § 1271.3(d), are subject to registration and listing under part 207 if they are drugs regulated under section 505 of the FD&C Act or under section 351 of the PHS Act. A conforming amendment is made to § 1271.1. Manufacturers of HCT/Ps that are regulated under section 361 of the PHS Act (42 U.S.C. 264) and not under section 351 will remain subject to registration and listing under part 1271.

(Comment 19) Comments requested clarification on the applicability of this rule to contract manufacturers and private label distributors of drug products, saying it was not clear in the proposed rule how contract manufacturers are to handle establishment registration and labeler code assignment.

(Response) Manufacturers of drug products are obligated by the FD&C Act and by this final rule—whether or not they are contract manufacturers—to register their establishments and list the drugs they manufacture for commercial distribution (as the term "commercial distribution" is defined in new § 207.1). Sections 207.49 and 207.53 of this final rule require manufacturers, repackers, and relabelers to provide their own NDC (an NDC that includes the registrant's own labeler code) for each drug they list. (Salvagers are not required to provide new NDCs when listing drugs they salvage because a drug's NDC does not change when it is merely salvaged, and not repacked or relabeled. A person who salvages and then repacks or relabels a drug is a repacker or relabeler, as those terms are defined in § 207.1, and must register and list as a repacker or relabeler.) This provision requires manufacturers, repackers, and relabelers responsible for listing drugs, including contract manufacturers, to obtain an NDC labeler code in accordance with new § 207.33(c).

When listing a human drug manufactured for private label distribution (distribution under the name or trade name of someone other than the drug's manufacturer, as defined in new § 207.1), §§ 207.49 and 207.53 require registrants to provide two NDCs, one that includes the registrant's own NDC labeler code and one that includes the NDC labeler code of the private label distributor. As stated in response to comment 16, FDA will accept drug listing information submitted by a private label distributor (or anyone else) if properly authorized to act as an agent for the actual manufacturer. The use of an agent to handle establishment registration or drug listing submissions does not, however, transfer legal responsibility for complying with this final rule from a manufacturer, repacker, relabeler, or salvager to its agent. Animal drugs manufactured for private label distribution should be listed under a single NDC that includes the labeler code of the private label distributor.

Note that the term "private label distributor" is defined in new § 207.1 to mean, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed. FDA's statements in this document that private label distributors are not obligated to register their establishments or list the drugs they distribute are premised on this definition. If someone who would otherwise qualify as a private label distributor carries out testing or control procedures applied to the final product, *e.g.*, systematic batch release testing required under current good manufacturing practices, that person may qualify as a manufacturer (see the definition of "manufacture" in new § 207.1) and need to register its establishment where the testing or control procedures are carried out. (But if a private label distributor uses a contract laboratory to carry out the testing or control procedures, the contract laboratory, not the private label distributor, may qualify as a manufacturer and need to register its establishment.) Likewise, if someone qualifies as a private label distributor with respect to one or more drugs, but also qualifies as a manufacturer, repacker, or relabeler with respect to other drugs, that person would need to register the establishment where manufacturing, repacking, or relabeling is conducted and list the drugs that are manufactured, repacked, or relabeled for commercial distribution at the registered establishment.

Entities that qualify as private label distributors under this final rule and do not also manufacture, repack, relabel, or salvage any drugs may already have effective establishment registrations and drug listings submitted in the past. We do not expect these entities to renew their registrations after the effective date of this final rule. They may either cancel their registrations or allow their registrations to lapse by not making any further submissions. Any drug listings submitted in the past by entities that qualify as private label distributors under this final rule for drugs they do not manufacture, repack, relabel, or salvage should be transferred to the actual manufacturers, repackers, relabelers, or salvagers of the listed drugs.

(Comment 20) One comment asked FDA to clarify whether radiologic products are subject to this rule.

(Response) This comment did not elaborate on the types of products encompassed by the question so we are unable to respond specifically. There is not an exemption from the establishment registration and drug listing requirements for manufacturers of radioactive drugs, also known as radiopharmaceutical products. Anyone with questions about the applicability of part 207, either before or after this final rule, to radioactive drug products should contact the electronic Drug Registration and Listing System staff in the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER). For diagnostic device products that include a radioactive drug constituent part, see our response to comment 22 in this document regarding drug/device combination products. Also see part 807 regarding establishment registration and listing for radiologic device products. Positron emission tomography (PET) drugs are subject to part 207, as stated in § 207.13(l)(1) and as discussed in the proposed rule (71 FR 51276 at 51285).

(Comment 21) One comment requested guidance regarding the information needed for "active drug substance manufacturers" to register and list.

(Response) In this final rule, the term "active pharmaceutical ingredient" (API) is defined in § 207.1. The registration obligation applies to each domestic establishment that manufacturers, repacks, relabels, or salvages a drug or an animal feed bearing or containing a new animal drug (whether or not that product is commercially distributed). It also applies to each foreign establishment that manufacturers, repacks, relabels, or salvages a drug or an animal feed bearing or containing a new animal drug that is imported or offered for import into the United States. In each case, the term "drug" includes: (1) An API by itself, (2) an API that has been combined with one or more other APIs or inactive ingredients (see definition of "unfinished drug" in § 207.1), and (3) finished drug products (see definition of "finished drug product" in § 207.1).

The information that must be submitted for establishment registration is set forth in new § 207.25. These information elements do not differ depending on whether the registrant handles APIs, other unfinished drugs, or finished drugs.

The information that must be submitted with a drug listing is set forth in new § 207.49 for a drug the registrant manufactures, § 207.53 for a drug the registrant repacks or relabels, and in § 207.54 for a drug the registrant salvages. As specified in § 207.41, the drug listing obligation applies only to drugs that are manufactured, repacked, relabeled, or salvaged for commercial distribution. Sections 207.49, 207.53, and 207.54 indicate some minor differences in the information that must be submitted depending on whether the drug is finished or unfinished. For example, § 207.49(a)(15)(iv) describes the labeling that must be submitted for an unfinished drug.

(Comment 22) One comment asked, in the context of the proposed rule's requirement that NDCs appear on drug labels, how the rule would apply to drug/device combination products. Other comments asked how registration and listing should be handled for drug/device combination product kits. (See the definition of "combination product" in § 3.2(e) (21 CFR 3.2(e)), unaffected by this rulemaking.)

(Response) We acknowledge that the proposed rule did not include an explanation of its applicability to drug/device combination products, including how manufacturers of such products should register their establishments, list their combination products, and provide related information on the labels of their combination products. The codified of this final rule likewise does not contain specific provisions regarding drug/device combination products. FDA expects to further address drug/device combination product registration and listing in the future. As stated previously in this document, we also are not finalizing the proposed amendment to § 201.2 that would have required human-readable NDCs on the labels of all drugs subject to the listing requirement.

3. Who is exempt from registration and listing requirements? (§ 207.13)

The proposed rule included a new § 207.13 aimed at clarifying the types of businesses that are exempt from drug establishment registration and listing under part 207. Section 207.13 is retained in this final rule with certain revisions and clarifications. Some exemptions described in § 207.13 are derived directly from section 510(g) of the FD&C Act. Other exemptions are established under section 510(g)(5) of the FD&C Act supported by our finding that registration by such classes of persons is not necessary for the protection of the public health.

(Comment 23) Several comments argued against the elimination of two existing exemptions from registration and listing that the proposed rule would have revoked. These two exemptions encompass: (1) Drugs imported under section 801(d)(3) of the FD&C Act (often referred to as "import for export") and (2) drugs that enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U.S. commerce.

(Response) Previous § 207.40(b) stated that no drug may be imported or offered for import into the United States unless the drug is listed and manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment. The section also stated that this prohibition did not apply to, among other things, components of drugs imported under section 801(d)(3) of the FD&C Act. Section 801(d)(3) allows persons to import certain articles, including components of drugs, if specified conditions are met, provided that the imported articles are further processed or incorporated into products and exported or, if not used, the imported articles are destroyed or exported. Thus, previous § 207.40(b) exempted certain foreign establishments from the establishment registration and listing requirement.

Previous § 207.40(a) stated that a foreign establishment was not required to comply with the registration and listing requirements if its drug entered a foreign trade zone and was re-exported from that foreign trade zone without having entered U.S. commerce.

Upon careful consideration of the comments received, we have decided to retain both exemptions in this final rule. Therefore, under § 207.13(j) of this final rule, if all the conditions of section 801(d)(3) of the FD&C Act are satisfied, a component of a drug will not be excluded from importation into the United States by reason that it is unlisted or was manufactured at an unregistered foreign establishment. Additionally, under § 207.13(j) of this final rule, a foreign establishment does not incur a registration and listing obligation if its drug enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U.S. commerce. These exemptions pertain only to drugs that are re-exported or components of drugs that are processed or incorporated into products and then exported, and these exemptions pertain only to foreign establishments. If an establishment located within a foreign trade zone manufactures, repacks, relabels, or salvages a drug for commercial distribution in the United States, that establishment would need to register and list those drugs it handles for U.S. commercial distribution. Additionally, if a foreign establishment exports drugs to the United States relying on either of these exemptions, but also exports other drugs for commercial distribution in the United States, it must comply with the registration and listing requirements for those drugs that are commercially distributed in the United States.

The corresponding exemptions for blood product establishments are also retained in § 607.40 under this final rule.

(Comment 24) One comment asked FDA to confirm that animal biological products are not subject to this rule.

(Response) Some biological drugs intended for administration to animals are regulated by the U.S. Department of Agriculture (USDA) under the Virus, Serum, and Toxins Act of 1913. Section 510.4 (21 CFR 510.4) states that animal drugs produced and distributed in full conformance with the Virus, Serum, and Toxins Act and any regulations issued thereunder shall not be deemed to be subject to section 512 of the FD&C Act (includes premarket approval and other requirements for new animal drugs regulated by FDA). As proposed in § 207.13(g), the final rule includes an exemption applicable to these products in § 207.13(h).

(Comment 25) Comments from the medical gas industry expressed concern about the ability of entities such as pharmacies, hospitals, clinics, and emergency responders to refill medical gas cylinders if the repackaging would require the repacker's NDC to appear on the label of the repackaged product. The comment stated that if these entities are exempt from part 207, they cannot obtain an NDC.

(Response) Our decision not to include the proposed amendments to § 201.2 that would have required human-readable NDCs on drug labels renders the concern expressed in this comment moot. We would like to confirm that pharmacies, hospitals, clinics, other health care entities, and public health agencies that qualify as exempt from the registration and listing requirements under § 207.13 of this final rule do not lose their exemptions by dispensing medical gases or filling medical gas containers in the normal course of their activities.

C. Registration (Part 207, Subpart B)

1. Who must register? (§ 207.17)

Section 207.17 describes who is required to register an establishment under part 207. This section is reworded in the final rule: (1) To distinguish between domestic and foreign manufacturers, repackers, relabelers, and salvagers and (2) to clarify that FDA will accept registration information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information pertaining to an entity that has an establishment registration obligation.

(Comment 26) One comment asked FDA to clarify whether a storage facility that does not repack or relabel drugs is required to register under part 207.

(Response) A facility at which drugs are stored, such as a warehouse, does not need to be registered provided drugs are not manufactured, repacked, relabeled, or salvaged (as those terms are defined in § 207.1) at the facility. Note that the definition of "manufacture" includes sampling, testing, or control procedures applied to the final product or to any part of the process. Thus, for example, if a warehouse includes a temperature-controlled storage area where drug samples are stored for stability testing to satisfy current good manufacturing practice requirements, that activity would qualify as a manufacturing operation and require registration of the warehouse as a drug establishment. Other State or Federal requirements may apply to such facilities.

As explained in response to Comment 17, we have revised the definitions of "relabel" and "relabeler" so they do not include the addition or modification of information affixed to drug packaging solely for purposes of delivery to a customer, customer identification, or inventory management. Therefore, the addition or modification of such information at a warehouse does not trigger the need to register it as an establishment.

2. When must initial registration information be provided? (§ 207.21)

Proposed § 207.21 described when initial registration information must be submitted for an establishment newly required to register under part 207. The provision is retained in this final rule and reorganized into paragraphs (a) and (b) for improved clarity.

(Comment 27) One comment suggested that the words "for commercial distribution" be added to § 207.21, suggesting that establishment registration is required only for establishments at which drugs intended for commercial distribution are manufactured, repacked, relabeled, or salvaged.

(Response) The absence of these words—"for commercial distribution"—from § 207.21 is intentional and comports with section 510 of the FD&C Act. Any establishment at which drugs are manufactured, repacked, relabeled, or salvaged must be registered under part 207, unless exempt from registration under section 510(g) of the FD&C Act or under the relevant regulations (§§ 207.13, 607.65, or 1271.15, as applicable) whether or not the drugs are commercially distributed. Accordingly, an establishment at which an investigational drug is manufactured is subject to the establishment registration requirement. The listing obligation, on the other hand, applies to drugs that are for commercial distribution.

3. What information is required for registration? (§ 207.25)

Proposed § 207.25 described the information that must be submitted to register an establishment. The provision is retained in the final rule with minor substantive and editorial revisions. Substantively, new § 207.25 no longer requires the submission of fax numbers to register establishments and now includes the new statutory requirement that registrants provide a UFI for each establishment. (See our discussion of establishment registration numbers and UFIs in section II.B, Changes to the Proposed Rule.) New § 207.25 also clarifies that the physical address of each establishment is required (rather than a post office box, for example), and a mailing address is required for the establishment's official contact.

(Comment 28) One comment asked FDA to clarify what format should be used when a foreign establishment submits contact information for each importer. This comment also asked FDA to explain who should submit establishment registration information when a business has both foreign and U.S. establishments.

(Response) According to new § 207.61, all information transmitted to FDA under part 207, including establishment registration information, must be transmitted to FDA in electronic format unless a waiver is granted. FDA's systems for electronic registration include fields for information elements such as the required contact information for U.S. importers of drugs manufactured, repacked, relabeled, or salvaged at a foreign establishment.

Section 207.17 addresses this comment's second question, who should submit establishment registration information when a business has both foreign and U.S. establishments? This section states that when operations are conducted at more than one establishment, and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments. This applies whether the establishments are domestic, foreign, or both.

(Comment 29) One comment asked FDA to exempt contract manufacturers from the requirement that establishments identify each importer in the United States of drugs they manufacture, repack, relabel, or salvage that is known to the establishment as well as each person who imports or offers for import such drugs to the United States. This comment stated that contract manufactures may not have this information.

(Response) This requirement is retained in the final rule, in § 207.25(h). The provision implements a statutory requirement (section 510(i)(1) of the FD&C Act). This requirement pertains only to foreign establishments, and it requires them to identify "importers" known to the establishment and "persons who import or offer for import," as these terms are defined in § 207.1. Both of these definitions have been refined and narrowed in this final rule. A foreign contract manufacturer exporting drugs to the United States should be able to identify such persons.

4. What are the requirements for reviewing and updating registration information? (§ 207.29)

Section 207.29 describes the requirements for: (1) Expedited updating of certain changes to establishment registration information and (2) annual reviewing and updating of establishment registration. This section is retained in the final rule with very minor revisions. Fax numbers are no longer mentioned in § 207.29(a) because they are no longer required for establishment registration. Additionally, the dates during which the annual review and update of registration information must take place have been adjusted to match section 510(b)(2) of the FD&C Act, added by FDAAA.

(Comment 30) Some comments opposed the requirement that if no changes have occurred since the last registration, registrants certify that no changes have occurred.

(Response) The annual review and updating of establishment registration information is critical to the integrity of FDA's database. The requirement that registrants certify that no changes have occurred when that is true provides important assurance that registrants have reviewed the establishment registration information they previously submitted. Otherwise, FDA would need to interpret silence from a registrant as indicating either that the information remains up to date or that the registrant may have neglected to review and update the information. We further note that section 510(b)(1) of the FD&C Act now requires annual registration of establishments between October 1 and December 31, and the option to certify that no changes have occurred since the last registration is a minimally burdensome implementation of this statutory requirement.

Please see our response to Comment 74, which addresses this issue in the context of drug listing updates.

D. National Drug Code (Part 207, Subpart C)

1. What is the national drug code (NDC), how is it assigned, and what are its requirements? (§ 207.33)

The NDC provisions in this final rule have been revised in response to comments received on the proposed rule. Most significantly, new § 207.33:

- Allows for 11 digits in the NDC (when 10-digit combinations are exhausted).
- Reflects that registrants will propose their own NDCs for drugs they

list. Under the proposed rule, FDA would have assigned NDCs in response to submissions from registrants. Under this final rule, each registrant must propose its own NDC for each drug the registrant lists. FDA will assign the proposed NDCs to the listed drugs unless they are improperly formatted, previously assigned to a listed drug, or reserved.

- Includes new NDC formatting requirements for registrants to observe when proposing NDCs.
- Transfers some information that would have been required under proposed § 207.33(c) (What information must a manufacturer submit before we will assign an NDC number to a drug?) to information that must be included in a drug listing submission.
- Allows certain drug products to be assigned alternatively formatted NDCs if approved by the Center Director. This applies to the HCT/Ps specified in new § 207.33(b)(4) if they are minimally manipulated.
- Includes a new § 207.33(c) that explains who must obtain an NDC labeler code and how labeler codes are assigned and updated.
- Includes new provisions in § 207.33(d) that explain how a proposed NDC can be voluntarily reserved.

Comments on the NDC provisions of the proposed rule and FDA's responses are summarized in this document. This does not include some comments that have been made moot by the revisions summarized previously.

(Comment 31) FDA received many comments opposing the proposed rule's requirement that FDA, rather than registrants, generate and assign the complete NDC for drugs that are subject to listing. Some comments were concerned about possible delays associated with NDC request submissions. Others were concerned about losing control over numbering conventions that individual registrants may apply to their own product codes and package codes. One comment expressed concern that subjecting OTC monograph products to an NDC assignment process could begin to resemble an FDA approval process for such products.

(Response) The objective behind FDA's proposal to generate and assign NDCs was to assure they are assigned appropriately. Although we did not intend FDA's issuance of NDCs to be time consuming or to operate as an approval process, we recognize that FDA's objectives can be met in a way that is more flexible and less burdensome for registrants. Accordingly, the proposed requirement that FDA generate the complete NDC for each listed drug is not included in this final rule.

Under new § 207.33(d), registrants, not FDA, will generate NDCs for assignment to their listed drugs. An NDC is considered to be "proposed for assignment" when a registrant submits it for the first time with drug listing information in accordance with § 207.49 or § 207.53. If the proposed NDC conforms to the formatting requirements of § 207.33, is not reserved for a different drug, and was not previously assigned to a different listed drug, FDA will assign the proposed NDC when it receives all required listing information for the drug.

(Comment 32) Some comments asked how far in advance of marketing a drug for the first time an NDC may be requested. Comments also pointed out that manufacturers need to know the NDC for a drug in development prior to the time of drug listing.

(Response) As explained in response to Comment 31, this final rule requires registrants to propose their own NDCs for drugs they list. FDA will assign a proposed NDC to the drug identified by the registrant if the proposed NDC conforms to the formatting requirements of § 207.33, is not reserved for a different drug, and was not previously assigned to a different listed drug.

We recognize that a mechanism for reserving a specific NDC may be helpful, as this would provide greater certainty that a proposed NDC will be accepted by FDA when it is included with a listing submission at the time of marketing. Accordingly, this final rule includes a new § 207.33(d)(3) that allows a person to voluntarily reserve a proposed NDC for a period of 2 years prior to its inclusion in a drug listing submission for the first time. Note that an NDC reserved under § 207.33(d)(3) would need to include most importantly a labeler code and a product code. At the discretion of the person submitting the reservation request, a single package code could be included, or not, with one or more package codes included later in NDC(s) submitted with complete drug listing information.

Certain minimal information must be submitted to reserve a proposed NDC, as specified in new § 207.33(d)(3). This information does not include identification of the drug's inactive ingredients. Many comments opposed the inclusion of such detailed information in the proposed rule's provision governing NDC requests.

NDCs reserved under § 207.33(d)(3) would be reserved for 2 years unless the person whose labeler code is included in the NDC asks FDA to cancel the reservation earlier. If a reserved NDC is not used during the 2-year reservation period (*i.e.,* is not submitted to FDA with complete listing information for the drug matching the reservation), the NDC will be available for assignment to another drug. Anyone wishing to extend an NDC reservation beyond 2 years may submit another reservation request.

In addition to the procedure established under § 207.33(d)(3), a registrant wishing to reserve an NDC also has the option of submitting complete listing information for a drug that is under development and specifying a future "start marketing date" in the listing submission. That listing submission could then be updated, as needed, when the actual marketing date arrives.

(Comment 33) One comment questioned how, when listing a drug for the first time, a registrant can supply a drug's labeling if the labeling must include the drug's NDC, and if the NDC is not assigned until the drug is listed.

(Response) As explained in response to Comment 1, unlike the proposed rule, this final rule does not require NDCs to appear in human-readable form on drug labels (but an intervening statutory amendment, the DSCSA, does require NDCs to appear as part of the product identifier on certain drug labels). After the effective date of this final rule, our regulations will continue to encourage, but not require, the appearance of human-readable NDCs on drug labels (§ 201.2) and continue to require that NDCs appear in bar codes on drug labels (§ 201.25(c)).

Under this final rule, unlike the proposed rule, registrants are able to develop and propose their own NDCs to FDA. Upon receipt of a first-time listing submission, FDA will assign the NDC proposed by the registrant to the drug being listed unless the NDC is improperly formatted, reserved for a different drug, or was previously assigned to a different listed drug. Registrants are also able to reserve an NDC for a drug under development under § 207.33(d)(3) of this final rule. Accordingly, registrants should not have difficulty determining, with adequate certainty, the NDC for a drug under development.

(Comment 34) Some comments supported the proposed rule's revocation of then-current § 207.35(b)(4)(ii), which stated that the product code of a discontinued product could be reassigned to another product 5 years after the expiration date of the discontinued product or, if there is no expiration date, 5 years after the last shipment of the discontinued product. Commenters generally agreed that the reuse of old NDCs for a different product in the future can be confusing. One comment, however, urged FDA to allow for the reuse of NDCs.

(Response) FDA is retaining this general prohibition against the reuse of NDCs in the final rule. As indicated in new § 207.33(d)(2), an NDC will not be assigned to a drug if it was previously assigned to a different drug. The prohibition against reuse of NDCs applies to listings submitted on or after the effective date of this final rule. Drugs that are currently listed under NDCs that have been reused in accordance with previous § 207.35(b)(4)(ii) may continue to be listed under such NDCs.

Conversely, if a registrant reintroduces a drug it listed and discontinued in the past, that registrant must list the drug using the same NDC under which it was listed in the past. See § 207.37(b) of this final rule. However, if the reintroduced drug includes changes, compared to the discontinued drug, that would warrant a new NDC under new § 207.35, then it should be listed under a new NDC.

As discussed in response to Comment 19, under new § 207.49, if a private label distributor uses a contract manufacturer to produce a human drug, the contract manufacturer has an obligation to list the drug under two NDCs, one that includes the labeler code of the contract manufacturer and one that includes the labeler code of the private label distributor. If the private label distributor switches to a new contract manufacturer in the future, that new contract manufacturer would also have an obligation to list the drug under two NDCs, one that includes its own labeler code and one that includes the labeler code of the private label distributor. The NDC that includes the new contract manufacturer's labeler code will obviously differ from the NDC under which the previous contract manufacturer listed the drug (because the labeler codes will differ). The NDC that includes the private label distributor's labeler code may be the same as that under which the previous contract manufacturer listed the drug provided: (1) There have been no changes to the drug that warrant a new NDC under § 207.35 and (2) the previous contract manufacturer updates its listing information to indicate it no longer manufactures the drug (as it is required to do under § 207.57 at the time of its next June or December listing update, or sooner at its discretion). If those two conditions do not exist, FDA would accept a listing from the new contract manufacturer under a new NDC that includes the private label distributor's labeler code.

(Comment 35) We received several comments concerning the format of the NDC. Many comments expressed concern about the impact of any changes in the NDC format on various systems that track and use NDCs. Some comments urged FDA to retain the 10-digit NDC format. Others encouraged the adoption of a standard 11-digit NDC. Some comments opposed the possible introduction of alphanumeric NDCs, preferring all numeric NDCs. Others were concerned about the possible coexistence of 10- and 11-digit NDCs.

(Response) FDA is sensitive to these concerns. Section 207.33(b) of this final rule specifies the format of an NDC recognized by FDA. The final rule necessarily includes more specifications than did the proposed rule concerning NDC formatting because under the final rule, registrants, not FDA, develop their own proposed NDCs, and they must all meet certain formatting parameters. The final rule states, for example, that the NDC is 10 or 11 digits to preclude the submission of longer NDCs.

Our regulations have long stated that FDA will expand the labeler code from five to six numeric characters when the available five-character code combinations are exhausted (previous § 207.35(b)(2)(i)). This occurrence is mathematically inevitable and is reflected in new § 207.33(b)(1), which states that the NDC must consist of 10 or 11 digits. FDA will begin issuing 6-digit labeler codes, leading to 11-digit NDCs, only when the available 5-digit labeler codes are exhausted. FDA will not assign 11-digit NDCs until we begin to issue 6-digit labeler codes.

FDA recognizes the desirability of a single, standard format for NDCs, having three segments of consistent lengths, as we eventually transition to six-digit labeler codes. We intend to initiate a public discussion of future formatting options in the near future. In the meantime, the provisions included in this final rule are intended to accommodate the range of existing NDC formats, leaving room for necessary expansion to 11 digits.

This final rule refers to the NDC as a numeric code, not an alphanumeric code. This takes into account comments that objected to the inclusion of alpha characters in NDCs as disruptive of current systems and practices.

(Comment 36) Some comments urged FDA not to require NDCs for HCT/Ps, citing the International Society of Blood Transfusion (ISBT) number as a better means of identifying these products.

(Response) In response to these comments, § 207.33(b)(4) of this final rule states that an alternatively formatted NDC may be used for certain identified HCT/Ps if they are minimally manipulated and if the alternatively formatted NDC is approved by the Center Director (CDER or CBER, as appropriate). Such approval may be indicated in Guidance for Industry issued by one or both Centers or in this preamble, for example. Accordingly, FDA identifies ISBT–128 as a currently approved alternatively formatted NDC to identify HCT/Ps within the scope of § 207.33(b)(4). ISBT–128 is an international standard for the identification of medical products of human origin. Please note that an alternatively formatted NDC approved under § 207.33(b)(4) qualifies as an NDC. HCT/Ps that are not within the scope of § 207.33(b)(4) require traditionally formatted NDCs.

(Comment 37) One comment encouraged FDA to allow a single NDC, with a single package code, to be assigned to an API, which may be commercially distributed in various quantities.

(Response) This comment refers to APIs, but the question applies to any bulk product supplied in variable quantities. We would like to accept non-numeric characters, such as one or more asterisks, in the package code segment of an NDC to indicate a bulk product supplied in various quantities (as was previously done in paper submissions). However, the SPL format, currently specified in the electronic registration and listing guidance, does not accommodate non-numeric characters. Manufacturers in this situation may adopt a variety of practices. They may submit multiple NDCs with package codes corresponding to a variety of commonly ordered package sizes. They may submit an NDC package code corresponding to 1 kilogram (kg), for example, and then treat a shipment of 10 kg as being comprised of 10 units. In some cases, they may submit an NDC with a package code corresponding to a 55-gallon drum, for example, and use that packaging to ship 55-gallon orders as well as orders that are slightly less than 55 gallons in volume.

(Comment 38) One comment recommended that the NDC for a drug that was repacked or relabeled include the product code of the source drug.

(Response) Section 207.53 of this final rule requires repackers and relabelers to list drugs they repack or relabel and requires them to submit an appropriate NDC for each such drug that includes the repacker's/relabeler's labeler code. It would not be feasible to require the NDC for a repacked or relabled drug to include the labeler code of the repacker or relabeler combined with the product code of the source drug. Such a requirement might produce an NDC that was previously assigned to a different drug. Because registrants will continue to propose their own NDCs under this final rule, a repacker or relabeler may generally adopt the convention proposed in the comment, but may not list a drug under an NDC that was previously assigned to a different listed drug.

Listing submissions for repacked or relabeled drugs must also include the complete NDC assigned to each finished drug received by the registrant for repacking or relabeling (*i.e.*, the source drug), so this link will exist in the drug's listing information.

(Comment 39) Two comments asked whether FDA will assign NDCs to products that do not have application numbers, *i.e.*, products that are not the subject of an approved application.

(Response) This question was posed in the context of the proposed requirement that registrants request an NDC from FDA by submitting information specified in proposed § 207.33(c) prior to a listing submission. In the case of finished drugs, proposed § 207.33(c) would have allowed registrants to submit an approved U.S. application number in place of certain information. As discussed in response to Comment 31, this final rule allows registrants to propose their own NDCs with listing submissions, and FDA will accept those proposed NDCs unless they are formatted incorrectly, reserved for a different drug, or previously assigned to a different drug. Under this final rule, NDCs are still "assigned" only by FDA, after all required listing information is received. We affirm that NDCs will be assigned in this manner to all drugs subject to the listing requirement, including drugs that do not have application numbers. As we have stated in the past (*e.g.*, previous § 207.39 and in the preamble to the proposed rule (71 FR 51276 at 51305)), FDA's assignment of an NDC does not in any way denote FDA approval of a product. Section 207.37 of this final rule states that a product may be deemed misbranded if an NDC is used to denote or imply FDA approval.

(Comment 40) Some comments asked how NDCs will be assigned to multidrug kits. Here we are addressing kits that do not contain medical devices. (See related discussion of drug/device combination products in response to Comment 22.)

(Response) If a product contains more than one finished drug product, co-packaged as a kit, and that kit is commercially distributed, the kit itself must be listed in accordance with § 207.41, under § 207.49 or § 207.53, as appropriate. A registrant submitting the listing should propose an NDC for the kit itself, distinct from any NDCs assigned to individual drug constituents contained in the kit. The NDC proposed for the kit should include the labeler code of the registrant obligated to submit the listing. If the kit is packaged for private label distribution, it should be listed under an additional NDC that includes the labeler code of the private label distributor.

(Comment 41) A comment asked whether a finished drug product, manufactured under one approved application at two different manufacturing sites under the same ownership and control could be listed under a single NDC. In this example, the finished product from each manufacturing site would have the same composition and physical appearance. The comment also asked whether the answer would change if the manufacturing sites are located in two different countries.

(Response) Each manufacturing site would need its own establishment registration under § 207.17 unless exempt under section 510(g) of the FD&C Act or under § 207.13. (Foreign establishments must register only if they manufacture, repack, relabel, or salvage drugs that are imported or offered for import into the United States.) With respect to the drug listing requirement, the proposed rule and the final rule specify in § 207.41(a) that when operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. This language allows a registrant that manufactures a drug at more than one of its own establishments to submit a single listing for that product, while identifying all establishments where the registrant manufactures the drug under § 207.49(a)(12). The listed drug would have a single NDC in this scenario. The answer does not change if one or more manufacturing sites are located outside the United States.

Note, however, that FDA would also accept multiple listings if a manufacturer in this situation wished for any reason to submit separate listings and NDCs for the same drug manufactured at multiple establishments.

This analysis does not apply to an entity that uses one or more contract manufacturers to manufacture, repack, relabel, or salvage a drug. In that case, each contract manufacturing site must be registered under § 207.17, unless exempt under section 510(g) of the FD&C Act or under § 207.13. If more than one contract manufacturing site is used, and those sites are under common ownership and control, the contract manufacturer could submit a single listing for this drug covering its activities at multiple sites (also listing other drugs it is required to list under § 207.49 or § 207.53). Furthermore, as discussed in our response to comment 19, contract manufacturers must generally list a drug under two NDCs, one that includes the contract manufacturer's labeler code and one that includes the private label distributor's labeler code. In this scenario, a single NDC that includes the private label distributor's labeler code could be used with a drug manufactured at multiple contractor sites along with a single NDC that includes the contract manufacturer's labeler code, provided there are no differences in the product produced at the various sites that would warrant a new NDC under § 207.35.

(Comment 42) One comment asked how registrants should assess whether their existing NDCs comply with this rule. Some comments noted a statement in the preamble to the proposed rule that FDA intends to validate that current NDCs comply with the new regulations when the rule is finalized (71 FR 51276 at 51280) and requested more information about this process.

(Response) This final rule is not intended to require extensive changes to NDCs themselves. The NDC formatting provisions of new § 207.33(b) are intended to accommodate NDC formats currently in use. The 10-digit NDC formats provided for under § 207.33(b) of this final rule include (in terms of numbers of digits in the labeler code, product code, and package code respectively) 4–4–2, 5–3–2, and 5–4–1. Any NDC in one of those formats that is not assigned to multiple drug products and is not assigned to a non-drug product should comply with this final rule. When five-digit labeler codes are exhausted, FDA will begin issuing six-digit labeler codes, allowing for additional formats of 6–3–2 and 6–4–1.

(Comment 43) Some comments encouraged FDA to permit one registrant or business to maintain more than one labeler code. These comments pointed out that mergers and acquisitions in the pharmaceutical industry result in corporate entities responsible for drugs listed under multiple NDC labeler codes. Consolidation of such NDCs to a single labeler code would be burdensome and may not be possible in some cases if, for example, one product code has been used with two different labeler codes.

(Response) FDA agrees with this comment. We encourage registrants and private label distributors to maintain a single labeler code wherever possible. But FDA will not require each registrant and private label distributor to maintain only one labeler code. This flexible approach accommodates mergers and acquisitions. It departs from a statement in the preamble to the proposed rule that only one labeler code would be used for new NDC numbers that FDA would have assigned prospectively for any given manufacturer, repacker, or relabeler (71 FR 51276 at 51299). It also accommodates situations in which any registrant wishes to maintain different labeler codes for different product lines or situations in which a registrant risks exhausting all available labeler code and product code combinations if the registrant operates with a single labeler code. Importantly, new § 207.33(c)(2) requires each person who is assigned a labeler code to update the information required under § 207.33(c)(1). This will allow FDA to reliably associate every labeler code with the person to whom it is assigned and the person's contact information.

Registrants and private label distributors who currently have NDC labeler codes but for whom FDA does not have up-to-date information described in § 207.33(c)(2) on the effective date of this rule are required to update their information. FDA may refuse to accept new drug listings that include an NDC labeler code for which the information required by § 207.33(c)(2) is not current in our system.

(Comment 44) One comment asked FDA to confirm that a business owning many registered establishments may maintain only one labeler code, so that all of its NDCs include a single labeler code.

(Response) FDA prefers that such a business maintain only one labeler code, and that it use this single labeler code when proposing NDCs for drugs it manufactures, repacks, relabels, or salvages at establishments under common ownership and control. However, as explained in our response to Comment 43, FDA will not require any business to maintain only one labeler code.

(Comment 45) One comment interpreted the proposed rule as preventing an entity that does not distribute its own products from maintaining its own labeler code. The comment recommended that such an entity not be required to assume distribution responsibilities to retain its labeler code.

(Response) FDA is not certain whether this comment is concerned with which NDC would have been required to appear on product labels had we finalized the proposed amendments to § 201.2, or more generally concerned with the NDCs under which private label distributor products are listed. Under § 207.33(c) of this final rule, a labeler code must be requested and maintained by any person who engages in manufacturing, repacking, relabeling, or private label distribution of drug products. The term "private label distribution" is defined in § 207.1 of this final rule to mean commercial distribution of a drug under the label or trade name of a person who did not manufacture, repack, relabel, or salvage that drug. A private label distributor does not need to physically engage in drug distribution to qualify as a private label distributor under this definition and maintain a labeler code under § 207.33(c).

(Comment 46) One comment gave an example of two establishments "located in the same geographical location within two cities located five miles apart" and asked whether those establishments would need separate NDC labeler codes and registration numbers.

(Response) Under the final rule's definition of "establishment," two establishments located 5 miles apart would not qualify as being at "one general physical location" and would therefore require two separate registrations. Each establishment would be associated with its own UFI and establishment registration number. As stated in § 207.17 of this final rule, when operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments. Likewise, with respect to drug listing information, § 207.41 states that when operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. A single labeler code may be used in the NDCs for all drugs proposed by such a parent, subsidiary, or affiliate company.

(Comment 47) A comment asked FDA to confirm that the NDC assignment requirement for APIs applies to all APIs, whether they are supplied by domestic or foreign establishments.

(Response) Any drug, including an API, manufactured at a domestic establishment for commercial distribution in the United States must be listed under § 207.49 unless exempt under § 207.13. As proposed and under this final rule, the registration and listing requirements apply to foreign establishments whose drugs, including APIs, are imported or offered for import into the United States. See §§ 207.13(j), 207.49, and 207.53.

(Comment 48) Some comments urged FDA to exempt allergenic extract products from the NDC requirement or from drug establishment registration and listing generally. These comments argued that the proposed rule would require manufacturers of allergenic extracts to manage a large number of NDCs without obvious benefits.

(Response) Allergenic extracts are used in the diagnosis and treatment of allergies. As such, they are appropriately regulated as drugs under the FD&C Act and FDA's regulations. Section 510 of the FD&C Act authorizes FDA to exempt certain persons from establishment registration (and hence listing) if registration "is not necessary for the protection of the public health." We decline to make this finding for allergenic extracts. Such an exemption would diminish FDA's ability to inspect establishments at which allergenic extracts are manufactured and track marketed products.

Both before and after this final rule, our regulations in part 207 have required that each listed drug product have an NDC. We understand that this requires manufacturers of allergenic extracts to associate a unique NDC with each product they manufacture for commercial distribution, and this may result in a large number of NDCs. We believe the public health benefits associated with drug registration and listing outweigh the burden this places on manufacturers to manage a large number of NDCs.

(Comment 49) One comment asked whether drug samples are subject to the NDC requirement.

(Response) Under this final rule, registrants must list drugs they manufacture, repack, relabel, or salvage for commercial distribution. The term "commercial distribution" is defined in a way that encompasses free samples. Because any listed drug requires an NDC, drugs packaged for distribution as promotional samples are expected to have NDCs.

(Comment 50) Some comments recommended that pharmacy compounded drugs be eligible for NDC assignment. These comments noted that hospital pharmacies use the NDC to reduce medication errors.

(Response) Drug products compounded by a licensed pharmacist or a licensed physician in conformance with section 503A of the FD&C Act are generally exempt from drug establishment registration and listing under part 207 before and after this final rule, consistent with the exemptions for pharmacies and practitioners in section 510(g) of the FD&C Act. The DQSA added section 503B to the FD&C Act. Under section 503B, a compounder can register with FDA as an ''outsourcing facility.'' Because the FD&C Act now establishes a separate registration and drug product reporting process for such outsourcing facilities, this final rule exempts outsourcing facilities from the registration and listing requirements of part 207. (See new § 207.13(k).)

Compounders that meet the conditions for exemption from registration and listing requirements under part 207 may elect to voluntarily register and list their products under part 207 and obtain NDCs.

2. What changes require a new NDC? (§ 207.35)

Section 207.33(f) of the proposed rule identified the types of changes to a drug that require a new NDC. This final rule includes new § 207.35 that states with greater clarity the types of changes to a drug that require a new NDC. Substantively, new § 207.35 is similar to the corresponding requirements in the proposed rule, but the provision does not require a new NDC when changes are made to inactive ingredients or when the Drug Master File number or Veterinary Master File number, if any, assigned to an API changes.

(Comment 51) Some comments were concerned about the types of changes to a drug that would require a new NDC in the proposed rule. In particular, many comments opposed the proposed requirement that changes in a drug's inactive ingredients would necessitate a new NDC.

(Response) This proposed requirement—that a change in a drug's inactive ingredients would necessitate a new NDC—has not been retained in the final rule. Under both the proposed rule and the final rule, any change in information submitted with a drug listing must be reflected in an updated listing under § 207.57. Certain more significant changes also require a new NDC, as specified in new § 207.35. Upon careful consideration, we agree with those comments that stated it would be unreasonably burdensome to require registrants to submit a new NDC each time they change the inactive ingredient composition of a product.

Some comments questioned the scope of the proposed requirement: Would it apply to changes from one inactive ingredient supplier to another? Would it apply to changes in the quantity at which an inactive ingredient is used? Would it apply to changes in the compositional specifications of an inactive ingredient?

The justification for this requirement suggested in the proposed rule was that some patients may be sensitive to certain inactive ingredients, and a change in NDC would flag for those patients and their pharmacists and health care providers that a drug's composition may have changed (or that some other characteristic identified in § 207.35 changed).

Upon careful consideration, we agree with those comments that challenged this justification. Paying attention to changes in NDCs would be an inexact way for patients, pharmacists, and health care providers to discover changes in inactive ingredients. As proposed and under this final rule, updates to drug listing information (including a new NDC) will be submitted each June and December, or sooner at the registrant's discretion. Thus, manufacturers will not be obligated to change an NDC immediately upon changing an inactive ingredient and update the NDC on their labels on a batch specific basis.

Comments pointed out that, particularly in the case of OTC monograph products, manufacturers currently have the flexibility to use certain inactive ingredients interchangeably. FDA's current guidance regarding the labeling of OTC drug products acknowledges this practice and includes formatting recommendations to accommodate the practice.[2] The proposed rule did not explain, for example, how the new NDC requirement would apply in a situation where the manufacturer of an OTC monograph product may have switched inactive ingredients in several different batches in the 6 months leading up to a semiannual listing update submission.

Rather than impose this burden on some manufacturers, and recognizing that ingredient labeling and reference to batch numbers are more useful and exact ways to ascertain a drug's composition, this final rule does not require a new NDC when a drug's inactive ingredients change.

(Comment 52) One group of comments expressed concern about the many situations in which a new NDC would be needed under the proposed rule. In addition to mentioning changes in inactive ingredients, the comments cited any addition to a drug's label or labeling, including the addition of stickers with delivery and handling instructions and ''any material change to a drug's labeling or packaging insert'' as things that should not warrant a new NDC. The comments emphasized the burden associated with changes to a drug's NDC.

(Response) Several changes in this final rule will reduce the number of occasions when a drug requires a new or additional NDC, compared to the proposed rule. See the response to comment 51 regarding changes to inactive ingredients. See our response to Comment 17 regarding the revised definition of ''relabel'' in the final rule to exclude the addition or modification of information affixed solely for purposes of delivery to a customer, customer identification, or inventory management. Under this final rule, changes or additions to a label that do not qualify as relabeling do not necessitate a drug listing submission and NDC under § 207.53. Section 207.35 of this final rule does not include ''any material change'' to a drug's labeling or package insert among the changes that necessitate a new NDC. Labeling changes are generally not included in new § 207.35. Some labeling changes will be incidental to the changes included in new § 207.35 (*e.g.,* a change to a drug's established or proprietary name), but labeling changes themselves do not trigger the need for a new NDC under this final rule. FDA has also determined that changes in Drug Master File numbers or Veterinary Master File numbers describing APIs, alone, should not necessitate new NDCs. Changes in APIs themselves, *i.e.,* a change in the identity of an API, will continue to necessitate new NDCs under new § 207.35.

(Comment 53) The Animal Health Institute noted that Animal Drug User Fee Act (ADUFA) fees are assessed for each animal drug NDC. This comment pointed out that manufacturers of animal drug products will be potentially charged twice for a single drug product due to a change in the NDC during a fiscal year or due to multiple listings for a single product required under this final rule. The comment urged FDA to exempt animal drug manufacturers from paying such extra product fees imposed by this final rule.

(Response) As noted in our response to Comment 52, several changes in this final rule will reduce the number of occasions when a drug requires a new or additional NDC, compared to the proposed rule. Under ADUFA, the term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the NDC, and for which an animal drug application or a supplemental animal drug application has been approved. See section 739(3) of the FD&C Act. Because product fees are assessed under ADUFA for animal drug products meeting this definition, fees are not assessed for unfinished animal drugs or animal drugs that are not marketed. However, there may be instances where a change is made to a marketed animal drug product that necessitates a new NDC for that product during a single fiscal year, resulting in a new ADUFA product fee. This is an issue that has existed prior to this final rule.

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[2] See the guidance for industry ''Labeling OTC Human Drug Products—Questions and Answers,'' December 2008, pp. 10–11, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs).

(Comment 54) One comment asked whether a new NDC will be required when a manufacturer changes to a new supplier of an API or, relatedly, whether multiple NDCs would be needed if multiple suppliers of an API are indicated in an approval application for a finished drug product.

(Response) Section 207.35 of this final rule requires a new NDC when there is a change to any API. This provision includes changes from one API to another (*e.g.*, a change from acetaminophen to ibuprofen) and changes in the strength of an API. The provision does not encompass changes in suppliers and does not require multiple NDC product codes corresponding to multiple API suppliers.

(Comment 55) One comment requested clarification regarding when a change in drug product strength will require a new NDC (or when multiple strengths will require multiple NDCs). This comment distinguished between concentration and strength.

(Response) Section 207.35 of this final rule requires a new NDC if the strength of any API changes. The term "strength" is generally used to refer to the absolute quantity of API in a single unit dose (*e.g.*, 250 milligrams (mg) per tablet). Concentration, on the other hand, refers to the amount of an ingredient per defined weight or volume of product (*e.g.*, 1 mg/1 milliliter (mL)). Examples of multiple strengths requiring separate NDCs include 100 mg/tablet, 250 mg/tablet, 1 mg/1 mL, and 2 mg/2 mL. Each of these would require its own NDC if each is supplied as a unit dose. This is true even though the last two concentrations are equivalent.

(Comment 56) Some comments questioned whether two digits are sufficient for the package code segment of the NDC. Relatedly, some comments requested clarification regarding the need for a new NDC when changes are made to a drug's package size or type. For example, would a change from one type of plastic bottle to another necessitate a new NDC? Another comment argued that changes in medical gas packaging should not necessitate many new NDCs.

(Response) A 2-digit package code segment accommodates 100 different packaging configurations, counting "00" as one possibility.

There should be a separate package code for each package size. Therefore, if a package is enlarged to hold more of a drug product, it would need a new NDC.

A change in package configuration, such as a change from a bottle to a blister pack, would also require a new NDC.

Under new § 207.35(c), a new NDC (specifically a new package code segment) is needed for changes in the composition of packaging material that are significant enough so that the packaging type description previously submitted is no longer accurate. When submitting drug listing information electronically, registrants are currently prompted to identify the package type by selecting a choice from a drop down list. For example, "Bottle, Plastic" is currently one available selection in the drop down list. If a registrant originally described its packaging material using this term and later switched from one type of plastic bottle to another, there would be no need for a new NDC. But if a change in packaging material is more significant, from plastic bottle to glass bottle, for example, so that a new package type should be selected from the drop down list, FDA would require a new NDC with a new package code segment to accompany the revised listing under § 207.35(c). (This discussion pertains only to drug listing obligations. Please see the FDA guidance for industry on "Container Closure Systems for Packaging Human Drugs and Biologics" (May 1999, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) regarding filing requirements for changes to container closure systems in the case of drug products that are the subject of an approved application (NDA, abbreviated new drug application (ANDA), or BLA)).

Medical gases are generally packaged in tanks, canisters, or cylinders. A registrant listing a medical gas would choose the appropriate packaging type from the drop down list, populated with such terms, in our electronic drug establishment registration and listing system. We do not currently require more detail about the composition of a tank, canister, or cylinder in which a medical gas is packaged and would not require a listing update or a new NDC if the composition of a tank, canister, or cylinder changes. Therefore, we do not anticipate an unreasonable proliferation of NDCs associated with medical gas packaging under this final rule.

If a registrant exhausts all 100 package codes for a single product, that registrant may add a second product code, effectively making 100 more package codes available. This provision is reflected in § 207.35(c) of this final rule.

(Comment 57) One comment stated that many minor changes are made to a drug's packaging, such as resin composition and size optimization. This comment stated that these minor changes are already the subject of submissions to FDA, for example, as an annual report (submitted under § 314.81(b)(2)), a prior approval supplement to an NDA, or a changes-being-effected supplement. This comment implicitly questioned the need for new NDC package codes triggered by these changes.

(Response) Section 207.35(c) of this final rule requires new NDCs, specifically new package codes, when changes are made to a drug's package size or type. See our response to comment 56 regarding our interpretation of this requirement. We acknowledge that certain postapproval packaging changes are reported to an NDA, BLA, or ANDA consistent with current § 314.70 and FDA *http://www.fda.gov/Drugss* guidance for industry "Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry Manufacturing, and Controls Documentation" (May 1999, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) and to a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA) consistent with current § 514.8 and FDA's guidance for industry "Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANDA" (May 2007, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)). These submissions, however, do not duplicate or satisfy the Agency's objectives behind drug listing and the use of the NDC to identify individual marketed drug products. These submissions also are not made for drugs that are not subject to the new drug approval requirements.

3. What restrictions pertain to the use of the NDC? (§ 207.37)

Proposed § 207.37 set forth restrictions pertaining to the use of NDCs. These provisions are retained in the final rule with minor revisions. New § 207.37 clarifies that a product improperly bearing an NDC may be deemed to be misbranded. Additionally, new § 207.37 is not addressed only to "manufacturers, repackers, and relabelers." Persons who are not subject to part 207 are cautioned against concluding that the restrictions stated in § 207.37 do not apply to them. Improper use of an NDC, as described in § 207.37, may result in a misbranding charge under the FD&C Act, whether or not the responsible party is generally subject to part 207.

(Comment 58) One comment agreed that NDCs should not appear in the labeling of dietary supplements, foods, and medical devices, but encouraged FDA to exercise enforcement discretion in this area. Other comments urged FDA to permit the use of NDCs on medical devices and medical foods. Others asked FDA to implement an alternative identification system for medical devices before finalizing this rule.

(Response) Section 207.37 of this final rule states that a product may be deemed to be misbranded if an NDC is used on the product but it is not subject to part 207. Since publication of the proposed rule, FDA has issued a final rule requiring UDIs on medical devices (78 FR 58786, September 24, 2013). Section 801.57 of that rule (21 CFR 801.57) generally prohibits the use of an NDC on the label of a medical device after the date on which it must bear a UDI.

The use of an NDC on the label of a product that is not regulated as a drug may confuse and mislead consumers and health care providers into believing FDA regulates the product as a drug. Any enforcement actions in this area will be subject to a determination that a product violates § 801.57 or is misbranded, or otherwise violates the FD&C Act.

(Comment 59) One comment argued against the proposed rule's prohibition against the use of NDCs on non-drug products and asked, if this prohibition is retained in the final rule, how long manufacturers of such products would have to remove NDCs from their labels.

(Response) Please see our response to comment 58 regarding the nature of § 207.37, specifically our clarification that the use of NDCs in the labeling of non-drug products may be handled as misbranding violations or as violations of § 801.57 as appropriate. See FDA's Unique Device Identifier rule (78 FR 58786) and any guidance FDA may issue regarding the compliance deadline for § 801.57. When an NDC in the labeling of a non-drug product creates the misleading impression that FDA regulates the product as a drug, that product may be subject to enforcement action.

E. Listing (Part 207, Subpart D)

1. Who must list drugs and what drugs must they list? (§ 207.41)

Proposed § 207.41 specified who must list drugs, and the provision is retained in this final rule. Section 207.41(c) now includes more detail about the manner in which drugs manufactured for private label distribution are listed.

(Comment 60) Some comments urged FDA to allow private label distributors to list drugs that are distributed under their names.

(Response) Please see our response to comment 16 regarding the definitions of "private label distributor" and "private label distribution" in § 207.1 for a discussion of the responsibilities of private label distributors in this final rule. Private label distributors are not obligated—by their status as private label distributors—to register an establishment or list drugs. They may, however, submit drug listing information or establishment registration information if acting as the authorized agent of a registrant on whose behalf the information is submitted.

2. When, after initial registration of an establishment, must drug listing information be submitted? (§ 207.45)

Proposed § 207.45 described an establishment's drug listing obligation at the time of initial registration. It stated that an establishment must, at the time of initial registration, list any drug then being manufactured, repacked, relabeled, or salvaged for commercial distribution at the establishment. Section 207.45 is revised in this final rule to state that such drugs must be listed no later than 3 calendar days after initial registration of the establishment.

(Comment 61) One comment encouraged FDA to provide flexibility in the timing of new drug listing submissions. The comment stated that it supported the current requirement of 5 calendar days from the start of manufacturing.

(Response) Several provisions of this final rule relate to the time periods within which establishment registrations, drug listings, and drug listing updates must be submitted. Section 207.21 states that domestic establishments must register for the first time no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug (whether or not commercially distributed). This 5-day window for initial establishment registration starts at the beginning of manufacture, not the beginning of commercial distribution. Section 207.45 states that each drug being manufactured, repacked, relabeled, or salvaged *for commercial distribution* at the time of initial registration must be listed no later than 3 calendar days after initial registration. Thus, the 3-day window established in § 207.45 relates to those drugs being manufactured at the establishment for commercial distribution at the time of initial registration. We will interpret the phrase "for commercial distribution" in § 207.45 flexibly as meaning immediate or near-term commercial distribution, not for storage prior to an initial product launch.

FDA recognizes that because it has made findings that nondisclosure of most drug listing information would be inconsistent with the protection of the public health (see § 207.81), registrants may be reluctant to list drugs that have not yet been commercially launched. FDA intends to interpret the timing requirements in a way that accommodates this concern. FDA also encourages and expects registrants to list drugs promptly upon commercial launch (following § 207.45 or § 207.57 as appropriate), recognizing that manufacturers have an incentive to list drugs promptly and have their proposed NDCs assigned by FDA. After a drug is listed, it should appear in our public NDC database within approximately 1 business day and in our internal database almost immediately.

3. What listing information must a registrant submit for a drug it manufactures? (§ 207.49)

Proposed § 207.49 identified the information that a registrant must provide with a drug listing submission for a drug it manufactures. Section 207.49 is retained and reorganized in this final rule. Some information included in proposed § 207.33(c) (what information must a manufacturer submit before we will assign an NDC number to a drug?) has been incorporated into new § 207.49 as drug listing information because it is not necessary under this final rule for manufacturers to request an NDC from FDA.

(Comment 62) One comment noted that an approved U.S. application number is included with drug listing information identified in § 207.49 and asked FDA to clarify whether an application must be approved before drug listing information is submitted.

(Response) Section 207.49(a)(7) of this final rule requires registrants to provide the approved U.S. application number with listing information for a drug if one exists. Thus, § 207.49 requires that an approved U.S. application number be provided with drug listing information only if it exists. Unapproved drugs can and must be listed without an application number.

Drugs that are the subject of an application need not be listed until they are manufactured for commercial distribution. Registrants who are awaiting approval of an application may voluntarily reserve an NDC for the drug that is the subject of the application prior to its approval under new § 207.33(d)(3). These registrants are also permitted, but not required, to list a drug before it is marketed, while providing a future start marketing date.

(Comment 63) Many comments opposed the submission of production volume information with drug listing information.

(Response) In the preamble to the proposed rule, FDA stated that it was considering whether to require establishments to provide the number of batches and batch size for each drug subject to the listing requirement that they manufactured, repacked, or relabeled since the establishment last provided listing information (71 FR 51276 at 51312). We have decided not to include such a requirement in this final rule.

(Comment 64) One comment urged FDA to eliminate the requirement that registrants submit representative samples of any other labeling for OTC drug products.

(Response) Section 207.49(a)(14)(ii)(b) of this final rule requires that for each human nonprescription drug not subject to section 505 of the FD&C Act or section 351 of the PHS Act (*i.e.,* not subject to premarket approval), drug listing information include the current label, the package insert (if any), and a representative sampling of any other labeling. The submission of ''any other labeling'' for such drugs is a requirement of section 510(j)(1)(B)(ii) of the FD&C Act.

(Comment 65) One comment questioned the proposed requirement that the ''drug facts'' labeling for OTC drug products be included in drug listing information, arguing that required labeling for OTC products is set forth in OTC monographs and in FDA's regulations in § 201.66.

(Response) We disagree with this comment. Section 207.49(a)(14)(ii)(B) of this final rule requires that labeling submitted with drug listing information for human nonprescription drugs not subject to section 505 of the FD&C Act or section 351 of the PHS Act include the ''content of labeling.'' This term is defined in § 207.1(b) to include, for these drugs, the drug facts labeling required by § 201.66. The submission of drug listing information is the only mechanism by which FDA has quick access to the labeling that is currently in use for marketed OTC drug products. Furthermore, section 510(j)(1)(B)(ii) of the FD&C Act requires that the label, package insert, and a representative sampling of any other labeling be provided with listing information for all such drugs, thus encompassing the drug facts labeling.

(Comment 66) One comment urged FDA to require that drug listing information for human OTC drugs include the current product label, but not other labeling. This comment also urged FDA to accept such labels in portable document format (PDF) files rather than structured product labeling (SPL).

(Response) As explained in response to Comments 64 and 65, the FD&C Act requires that drug listing information for OTC human drugs not subject to section 505 of the FD&C Act or section 351 of the PHS Act include the label, package insert, and a representative sampling of ''any other labeling.'' Therefore, this comment's recommendation that only the current product label (*i.e.,* the container label) be submitted for such products is contrary to the FD&C Act, and we decline to adopt it. Drug listing information is the only mechanism by which FDA collects labeling for such products, and it is important that we have it readily available.

This final rule does not specify a file format for the submission of drug listing information, but it does require electronic submission in a format FDA can ''process, review, and archive.'' (See § 207.61(a) of this final rule.) As explained in our electronic registration and listing guidance, to facilitate the submission of drug establishment registration and drug listing information (including the content of labeling), FDA has adopted the use of extensible markup language (XML) files in a standard SPL format. The automated submission process functions most efficiently and effectively when this information is provided in a standardized format with defined code sets and codes. Information in a properly created and complete SPL file can facilitate processing and allows for greater precision and accuracy through the use of coded data fields rather than merely electronic text. For these reasons, we will continue to expect drug listing information in SPL format.

In the case of unfinished drugs, § 207.49(a)(15)(iv) requires submission of the label (if any) but does not require registrants to submit the content of labeling. Because FDA does not currently electronically process the labels submitted for unfinished drugs, we have accepted and will continue to accept electronic submission unfinished drug labels in JPEG (Joint Photographic Experts Group) file format.

(Comment 67) One comment questioned the proposed requirement that drug listing information include the name of each inactive ingredient in a listed drug. Another comment argued that drug listing submissions for animal drug products in particular should not be required to identify inactive ingredients.

(Response) This requirement is retained in the final rule, specifically in new § 207.49(a)(5), applicable to both human and animal drugs. FDA finds it important to maintain up-to-date inactive ingredient information for all marketed drug products. This allows FDA, for example, to determine the extent to which a particular inactive ingredient is currently in use and identify drug products that contain it. FDA does not have access to this information in the form of a searchable database outside of our drug registration and listing information.

(Comment 68) We received several comments pertaining to the drug listing obligations of contract manufacturers, contract packagers, and contract laboratories. One requested clarification regarding the manner in which a contract manufacturer or packager would submit listing information for an investigational drug manufactured or packaged for use in a clinical trial.

(Response) Contract manufacturers, packagers, and laboratories—unless they are exempt under section 510(g) of the FD&C Act or § 207.13—will generally qualify as manufacturers under this final rule and will be required to register their establishments. Under § 207.41 of this final rule, registrants must list drugs they manufacture, repack, relabel or salvage *for commercial distribution.* The definition of ''commercial distribution in new § 207.1 excludes drugs distributed for investigational use under part 312 (21 CFR part 312) or part 511 (21 CFR part 511). The drugs referred to in this comment may be exempt from listing under this analysis.

(Comment 69) Another comment asked how a contract manufacturer or packager should be expected to submit twice annual drug listing updates, attesting for example that there have been no changes to a drug's labeling, when the contract manufacturer or packager is not responsible for or aware of labeling changes in the ordinary course of its business.

(Response) This comment relates to a wide variety of situations. We recognize that contractors play an important role in drug manufacture. Some perform specialized operations for another manufacturer (*e.g.*, blister packaging), and others perform all manufacturing operations for a virtual drug company. Some contract manufacturers handle drugs that are the subject of an approved application and are sold under the name of the application holder. Others manufacture OTC drugs for multiple private label distributors. Each situation will require its own analysis under this final rule, and there may be more than one way to satisfy the rule's requirements.

If a contract manufacturer is performing one or more steps in a larger manufacturing operation, it may be shipping an unfinished drug to another contracting party. In that case, the contract manufacturer would submit listing information under § 207.49 for the unfinished drug it distributes commercially, *i.e.*, the unfinished drug that leaves its registered establishment(s). This would include labeling information required under § 207.49(a)(15)(iv), meaning the label applied to the unfinished drug. In this scenario, the contract manufacturer would not be responsible for listing updates that describe labeling changes for the finished drug product, if the contract manufacturer does not commercially distribute the finished drug product.

If a contractor is performing all steps or just the final steps in a drug manufacturing process, the contractor should describe the finished drug product in its listing submission. In some cases, a contract manufacturer may be responsible for formulating the product and developing its labeling. This might be true in the case of an OTC store brand, private label distribution product, for example. In that situation, the contracting parties would likely agree that the contract manufacturer is in the best position to submit drug listing information and updates (as it is required to do under this final rule), and this would include the submission of any labeling changes with twice annual listing updates. In other cases, a contractor might play a much smaller role. It might only place a product manufactured and developed by someone else into its final packaging. In that case, the contractor would be required by this final rule to submit listing information pertaining to the finished drug product, including the twice annual updates. The contractor might satisfy this obligation by consulting with the drug's developer about any changes in drug listing information or by letting the drug's developer act as its authorized agent for the submission of drug listing information and updates. At all times, however, the actual manufacturer of a drug (or repacker, relabeler, or salvager) is legally responsible for ensuring that the requirements of this final rule are satisfied.

(Comment 70) One comment stated that "the proposed requirement for finished product contract testing laboratories to list all of the products they test should be eliminated." The comment pointed out that testing laboratories only handle representative samples of products that do not enter the supply chain.

(Response) This comment addresses an issue that arises under the FD&C Act and the drug registration and listing regulations as they have long existed. (See the definition of "manufacturing or processing" that has existed in § 207.3 prior to this final rule.) Testing laboratories, whether they test finished drug products or in-process materials, may have important roles in drug manufacturing and are appropriately treated as manufacturers under part 207 if they engage in testing or control procedures necessary for manufacture under current good manufacturing practices. Any testing laboratory that qualifies as a "manufacturer" under this final rule must register its establishment(s) where drugs are tested. The listing obligation, however, applies only to drugs that a registrant places into commercial distribution. Therefore, if a laboratory tests in-process materials or finished product and then commercially distributes the tested product, *e.g.*, for further processing or for distribution as finished product, that laboratory would have an obligation to list the drugs it commercially distributes. More likely, however, if the laboratory merely tests product samples and reports the test results to another party without further distributing the tested samples, it has no listing obligation.

(Comment 71) One comment expressed concern that importers would have to identify manufacturers for their drug components and provide a chain of custody description for each handler from manufacturer to importer.

(Response) This comment reflects a misunderstanding of a statement in the proposed rule describing section 801(d)(3) of the FD&C Act. To clarify, § 207.49(a)(12) of this final rule requires a registrant listing a drug it manufacturers to provide: (1) The name and UFI of the establishment where the registrant manufactures the drug and (2) the name and UFI of every other establishment where manufacturing is performed for the drug. With respect to this second category of information, if the registrant provides a properly assigned and listed NDC for unfinished drug(s) it uses to produce the listed drug (sometimes referred to as "immediate source NDCs"), the registrant does not need to provide names and UFIs of the upstream establishments.

(Comment 72) One comment asked FDA to clarify a statement in the preamble of the proposed rule regarding certificates of analysis for imported articles.

(Response) This comment reflects a misunderstanding of the proposed rule. The passage it refers to quotes section 801(d)(3) of the FD&C Act (71 FR 51276 at 51284). Section 801(d)(3) of the FD&C Act applies only to certain imported products, and this final rule does not implement it.

4. What listing information must a registrant submit for a drug it repacks or relabels? (§ 207.53)

Proposed § 207.53 identified the information that a registrant must provide with a listing submission for a drug it repacks or relabels. Section 207.53 is retained and reorganized in this final rule. Some information included in proposed § 207.33(d) (What information must a repacker or relabeler submit before we will assign an NDC number to a drug?) has been incorporated into new § 207.53 as drug listing information because it is not necessary under this final rule for manufacturers to request an NDC from FDA.

(Comment 73) A comment from the medical gas industry expressed concern about the proposed rule's requirement that repackers identify, in drug listing information, the NDC associated with a drug immediately before it is received by the repacker for repackaging. This comment argued that the complexity of medical gas distribution makes this requirement difficult to satisfy.

(Response) We agree that medical gas repackers would need to significantly change the way they currently do business to identify immediate source NDCs as specified in the proposed rule. In response to this comment, we have included an exception in § 207.53 of this final rule so that repackers and relabelers of medical gases are not required to include with drug listing submissions the NDC assigned to each medical gas they receive for repacking or relabeling.

5. What are the requirements for reviewing and updating listing information? (§ 207.57)

Proposed § 207.57 described the requirements for reviewing and updating drug listing information. The provision is retained in this final rule with editorial revisions intended to improve clarity. Additionally, the section now says registrants are encouraged to submit listing updates at the time of any change affecting previously submitted information. We have also deleted a reference to § 207.55. Under § 207.55, FDA may ask a registrant to explain the basis for its belief that a drug is not subject to approval. We do not expect registrants to routinely update information provided to us under § 207.55.

(Comment 74) Some comments opposed the requirement that to satisfy the June and December listing update obligation, registrants must certify that no changes have occurred if no changes have occurred since the last review and update of listing information.

(Response) The preamble to the proposed rule specifically requested comments regarding the burden that may result from the no changes certification requirement in the context of drug listing updates (71 FR 51276 at 51314). We have retained in this final rule the requirement in § 207.57(b) that registrants update their submitted drug listing information each June and December. The review and updating of drug listing information is critical to the integrity of FDA's database. We recognize, however, that requiring registrants to submit a twice-annual "no changes" certification, on a product-by-product basis, for each of their listings would impose a substantial burden on registrants, particularly those that maintain hundreds or thousands of drug listings. Therefore, § 207.57 of this final rule requires registrants to report changes to drug listing information either at the time of any change affecting information previously reported or during the next June or December listing update following the change. At the time of the annual registration update under § 207.29(b), a registrant may submit a blanket "no changes" certification covering all of its listed drug products for which no changes affecting previously reported listing information were made since the last annual registration update or listing submission. This blanket, "no changes" certification applies only to drug listing information that has been submitted electronically, as it would be too burdensome for FDA to maintain certifications for information that has not been submitted electronically. Therefore, it cannot be used to report that drug listing information submitted on paper in the past remains current. This limitation is intended to ease FDA's administrative burden and allow FDA to consider drug listing information to be fully migrated from paper submissions to our electronic drug registration and listing system.

Please see our response to Comment 30, which addresses this issue in the context of establishment registration updates.

(Comment 75) One comment stated that the obligation to provide updates on individual drug listings within 30 days will demand a great deal of resources from manufacturers.

(Response) This comment did not cite the specific provision of the proposed rule at issue. The preamble to the proposed rule acknowledged that proposed § 207.57(b) would require that drug listing information be reviewed and updated only every June and December, but also stated that FDA would request updates to listing information within 30 calendar days of a change, to maintain the accuracy of our drug listing database (71 FR 51276 at 51314). Under § 207.57 of this final rule, registrants are encouraged to submit updated drug listing information at the time of any change affecting information previously submitted, but they are required to submit such information only every June and December.

(Comment 76) Two comments asked FDA to clarify whether a registrant may report all changes to drug listing information when they occur, *i.e.*, on a rolling basis, instead of conducting a review and update each June and December.

(Response) Under § 207.57 of this final rule, registrants must review and update their drug listing information each June and December. This is a requirement of section 510(j)(2) of the FD&C Act. Registrants are additionally encouraged, but not required, to update drug listing information at the time when changes are made to previously reported information. These updates do not, however, take the place of the June and December updates, which may be satisfied by a no changes certification if no changes have occurred since the last review and update. We will read "since the last review and update" in § 207.57(b)(2) as referring to the registrant's most recent listing update for a given drug, whether submitted in June, December, or at any other time.

(Comment 77) One comment encouraged FDA to codify a registrant's ability to submit updated listing information at the time a change is made, rather than waiting for the next June or December review and update. This comment referred to a statement in the preamble to the proposed rule stating that registrants are requested to submit listing information within 30 days of a change.

(Response) We agree with this comment and have revised § 207.57 accordingly. New § 207.57 states that registrants are encouraged to submit listing updates at the time of any change affecting information previously submitted. This provision of the final rule does not refer to a 30-day window for such listing updates. We intend to read "at the time of any change" flexibly, encouraging registrants to submit listing updates as soon as possible, but allowing such updates at any time before they are due at the next June or December review and update.

(Comment 78) One comment expressed concern regarding the manner in which a drug's discontinuation is to be reported under § 207.57. This comment noted that historically, many registrants have waited to report that a drug has been discontinued until they no longer have to report the drug under applicable agreements with the Centers for Medicare and Medicaid Services. According to this comment, if an NDC is identified as discontinued while the drug is still in distribution up until expiration, there may be problems related to reimbursement and other matters.

(Response) The FD&C Act and § 207.57 of this final rule require listing updates, including information that a drug has been discontinued, at the latest, at the time of the next June or December review and update following the discontinuation. In the case of drugs that are subject to part 314, § 314.81(b)(3)(iv) also requires that their withdrawal from sale be reported to FDA. The reporting deadline under § 314.81(b)(3)(iv) is within 15 working days of the withdrawal from sale before the effective date of this final rule and within 30 calendar days of the withdrawal from sale after the effective date of this final rule. It is important that FDA receive this information soon after discontinuation for the integrity of our database.

In this final rule, as in the proposed rule, § 207.57 requires registrants, when reporting that a listed drug has been discontinued, to provide the expiration date of the last lot manufactured, repacked, relabeled, or salvaged. FDA regards this date as the "end marketing date" and includes it in the public NDC database when a drug is reported to be discontinued.

Please note that, in addition to the requirements just discussed, section 506C of the FD&C Act, as amended by FDASIA, requires manufacturers of certain drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, to notify FDA of a permanent discontinuance or certain interruptions in manufacture at least 6 months prior to the date of discontinuance or interruption or as soon as practicable if 6-month's prior notice is not possible.

(Comment 79) Two comments opposed the requirement in § 207.57 that registrants provide, for a discontinued drug, the expiration date of the last lot manufactured, repacked, relabeled, or salvaged, arguing that the expiration date of the last lot provides no assurance that the drug product will be available to consumers until that date is reached.

(Response) As explained in response to Comment 78, our use of the expiration date of the last lot as an "end marketing date" facilitates reimbursement while remaining stock of a discontinued drug works its way through distribution.

(Comment 80) Two comments requested clarification regarding how the inclusion of an approved application number in a drug listing submission can take the place of the content of labeling in SPL format, specifically how updated labeling would be provided at the time of a listing update if only the application number is referenced.

(Response) The proposed rule indicated that if "a manufacturer provides a drug's approved U.S. application number as part of a drug's listing information, the labeling required under proposed § 207.49(g)(1) and . . . 207.49(g)(2) would be deemed to accompany the listing information" (71 FR 51276 at 51309). This was written prior to FDA's adoption of SPL as the submission standard and is not an accurate reflection of how the process operates today. However, FDA has considered how our electronic system can avoid unnecessary duplication of effort between the submission of labeling updates to applications and the submission of drug listing information.

Under this final rule, a drug listing submission, whether it includes an approved application number or not, must include content of labeling as specified in § 207.49. An advantage of the SPL format is that it allows the holder of a newly approved application to submit the content of labeling once, satisfying its obligations under parts 314 and 207 in a single submission. Upon initial approval, an applicant is required to submit a copy of final approved labeling. An electronic drug listing submission that includes the content of labeling in SPL format can satisfy this obligation. Even if the drug product is not yet ready for commercial distribution upon approval, SPL allows for a future start marketing date in the listing information so that a second submission is not necessary when the product is commercially launched.

As discussed in response to Comment 15, most drug labeling changes necessitate a listing update under § 207.57 of this final rule. Registrants who submit drug listing information through FDA's CDER Direct electronic submission portal (as well as those using some commercial software) will be able to recall a previous submission, including the content of labeling, and make appropriate changes when a listing update is due. But reference to an application number alone will not satisfy the requirement that updated content of labeling be submitted under § 207.57 in this final rule.

F. Electronic Format for Registration and Listing (Part 207, Subpart E)

Proposed § 207.61 stated that establishment registration and listing information must be submitted to FDA electronically. As proposed, § 207.61 would have allowed advertisements and some labeling to be submitted to FDA either in paper or electronic format. In this final rule, § 207.61 is revised for clarity. Additionally, the final version of § 207.61 requires electronic submission of all establishment registration and listing information, consistent with FDAAA (no longer allowing for the submission of advertising on paper), unless a waiver is granted, and states that FDA may issue guidance from time to time on how to provide information in electronic format. Because the SPL format currently used for electronic submission of registration and listing information does not accommodate the submission of drug advertising, taking into account various types of advertising media currently in use, FDA is not currently collecting advertisements as part of drug listing information. If this technical limitation is resolved, we will explain in future guidance how and what registrants should transmit electronically as a representative sampling of advertisements. In the meantime, we may ask individual registrants to submit a representative sampling of advertisements for specific prescription human drug products not subject to section 505 of the FD&C Act, relying on our authority under section 510(j)(1)(B)(i) of the FD&C Act and § 207.49(a)(14) of this final rule.

The final version of § 207.61 also clarifies that, while drug registration and listing information must generally be submitted in the English language, in some cases the content of labeling may be submitted in a foreign language along with an accurate English translation.

(Comment 81) One comment stated that information should be included in the final rule to address whether FDA intends to develop a separate database for animal health products or incorporate animal drugs into the proposed electronic drug registration and listing database. The comment recommended that if a separate database is planned, information on whether the same data elements will be required to obtain an NDC number and list products would be helpful.

(Response) At issue in this rulemaking are changes to FDA's regulations governing drug establishment registration and listing, *i.e.,* changes to the codified language presented in the proposed rule and in this final rule. These regulations do not describe the electronic drug registration and listing systems developed by FDA, which may change from time to time. Currently, FDA maintains separate electronic systems for establishment registration and listing for human drugs and for animal drugs. The information that must be submitted with a drug listing submission, for both human drugs and animal drugs, is described in the regulations codified in part 207 as amended by this final rule.

(Comment 82) One comment noted that at the time of the proposed rule and the comment period, FDA's electronic drug registration and listing system had yet to be developed. Accordingly, stakeholders were unable to comment on an electronic system that had yet to be developed.

(Response) We understand stakeholder interest in the development of our electronic system for drug registration and listing. As noted in response to Comment 81, however, the amended regulations adopted in this rulemaking do not describe the electronic drug registration and listing systems developed by FDA. They generally describe information that must be submitted to FDA, and they require that it be submitted electronically. Therefore, the proposed rule did not solicit comments on the electronic drug registration and listing system then under development.

After the proposed rule was published, Congress amended the FD&C Act to require electronic submission of drug establishment registration and listing information. To implement this statutory change, FDA published draft guidance in 2008 and final guidance in 2009 concerning electronic submission of drug establishment registration and listing information. Stakeholders had an opportunity to comment on the electronic system described in our draft guidance and, as with all FDA guidance, have an ongoing opportunity to comment at any time.

FDA currently accepts drug establishment registration and drug listing information submitted electronically. We expect registrants to find electronic submission less burdensome than the use of paper forms, and we accept comments and suggestions from stakeholders regarding improvements to our electronic submission systems.

(Comment 83) One comment recommended that to facilitate the annual review and updating of both establishment registration and drug listing information, FDA provide registrants with a report of their current registration and listing information.

(Response) This comment does not relate to language that would be included in the codified portion of this final rule, but it does raise an important issue we would like to address. At all times, registrants are responsible for keeping track of registration and listing information they have submitted to FDA and should ensure the information is securely stored and can be retrieved.

Registrants who use an agent to submit establishment registration and drug listing information to FDA are encouraged to maintain their own records of the submitted information or obtain assurances that the agent will do so and will make the information available to the registrant on request, including if their business relationship is terminated.

FDA currently maintains publicly searchable databases that can be used to confirm an establishment is registered. Information about registered blood establishments is available through FDA's electronic Blood Establishment Registration (eBER) public query application. Information about registered HCT/P establishments is available through the Human Cell and Tissue Establishment Registration (HCTERS) public query application. Information about registered drug establishments can be obtained through FDA's Drug Establishments Current Registration Site (DECRS). Additionally, FDA's NDC Directory currently includes listed finished drug products, but not unfinished drug products. It may be expanded in the future to include all listed drugs. Registrants can check these sources and may also request a report of their own registration and listing information from CDER's Drug Registration and Listing staff.

(Comment 84) Comments noted that changes to part 11 (21 CFR part 11) are being considered by the Agency and recommended that electronic submission of drug registration and listing information be delayed or exempt from compliance with part 11 until these changes have been decided.

(Response) Because of changes to section 510(p) of the FD&C Act adopted in FDAAA, registration and listing information is currently submitted electronically. Exceptions from the electronic submission requirement will be handled in accordance with the waiver provisions in this final rule (§§ 207.65, 607.22, and 1271.23).

Part 11 sets forth criteria under which FDA considers electronic records and signatures to be trustworthy and reliable. Part 11 applies to electronic records that are created, modified, maintained, archived, retrieved, or transmitted under statutory and regulatory requirements. In 2003, FDA published guidance for industry titled "Part 11, Electronic Records; Electronic Signatures—Scope and Application" (2003 Part 11 Guidance, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) and announced its availability in the **Federal Register** (68 FR 52779, September 5, 2003). This guidance announced a reexamination of part 11, a narrow interpretation of its scope, and a policy of enforcement discretion with respect to certain of its requirements. Part 11 currently remains in effect, and FDA's policy of enforcement discretion applies as described in the guidance.

Against this backdrop, the proposed rule included a discussion of how FDA intended to apply part 11 to electronic drug registration and listing. (See 71 FR 51276 at 51317.) Proposed §§ 207.61, 607.22, and 1271.22 specified that certain requirements of part 11 would not apply to information submitted to FDA under parts 207, 607, and 1271. In § 207.61 of this final rule, the applicability of part 11 is stated as follows: The submission of advertisements and labeling is exempt from the requirements of § 11.10(a), (c) through (h), and (k) and the corresponding requirements of § 11.30. Other information submitted under part 207, as well as information submitted under parts 607 and 1271, is exempt from the requirements of § 11.10(b), (c), and (e) and the corresponding requirements of § 11.30. These statements in the codified portion of this final rule are intended to be read together with any current FDA guidance concerning our enforcement of part 11. For example, FDA's 2003 Part 11 Guidance states that we do not intend to take action to enforce compliance with the validation and audit trail requirements of part 11. This includes requirements described in § 11.10(a) and (e). Until our 2003 Part 11 Guidance is withdrawn or modified, these statements regarding enforcement discretion remain current. Therefore, any person submitting information electronically to FDA under this final rule may rely on the exemptions from part 11 written into parts 207, 607, and 1271, in addition to statements regarding part 11 enforcement discretion in current FDA guidance.

(Comment 85) One comment noted that a citizen petition is currently pending before FDA requesting that part 11 be revoked in its entirety (Docket No. FDA–2004–P–0036, formerly Docket No. 2004P–0429/CP1). This comment asked FDA to respond to the citizen petition before it completes this rulemaking.

(Response) The referenced citizen petition remains under review, and the part 11 regulations are currently being implemented as explained in FDA's 2003 Part 11 Guidance. FDA's publication of this final rule should not be interpreted as providing any indication of the manner in which the citizen petition will be resolved.

G. Miscellaneous (Part 207, Subpart F)

Section 207.81 of the proposed rule identified establishment registration and listing information that will be available or not available for public disclosure after it is submitted to FDA. Section 510(f) of the FD&C Act states that establishment registration information is available for inspection and drug listing information is generally not available for inspection unless the Secretary (by delegation FDA) finds that an exemption from disclosure would be inconsistent with protection of the public health. Consistent with this statutory provision, proposed § 207.81 stated that establishment registration information would be generally available for disclosure and that most, but not all, drug listing information would be available for disclosure, as its nondisclosure would be inconsistent with protection of the public health. Generally categorized as not available for disclosure in the proposed rule was information obtained under:

- Proposed § 207.33(d)(1)(ii)—Source NDCs for repacked or relabeled drugs submitted in the context of an NDC request for such drugs,
- Proposed § 207.54(b)(1)—Source NDCs for salvaged drugs, and
- Information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the FD&C Act, the premarket approval requirement for new drugs and new animal drugs.

In this final rule, § 207.81 has been revised in several ways. The section has been reorganized so that registration and listing information that will be available for public disclosure is identified in paragraph (a), and exceptions are identified in paragraphs (b) and (c). Cited section numbers have been revised, consistent with the renumbering of sections in this final rule (and the shifting of some information required in the proposed rule as supporting an NDC request to information required in the final rule as drug listing information). Substantively, § 207.81 of this final rule identifies an expanded set of information obtained under the following sections as information that will not be available for public disclosure:

- § 207.53(b)—Immediate source NDCs for repacked or relabeled drugs;
- § 207.54(a)—Immediate source NDCs for salvaged drugs;
- § 207.54(c)—The name or UFI of an establishment where a specific drug is salvaged;
- § 207.55—Information submitted as the basis upon which it has been determined that a particular drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;
- § 207.33(d)(3)—Information submitted to reserve an NDC;
- § 207.49(a)(9)—For unfinished drugs, the number assigned to the Drug Master File or Veterinary Master File, if any;
- § 207.49(a)(12)—The names and UFIs of establishments where manufacturing is performed for listed drugs and/or immediate source NDCs;
- § 207.53(c)—The names and UFIs of establishments where repacking or relabeling is performed for listed drugs; and
- § 207.49(a)(5)—The names of any inactive ingredients submitted with drug listing information for which the registrant makes a valid assertion of confidentiality.

In this final rule, establishment registration information will be available for disclosure, consistent with section 510(f) of the FD&C Act, except in limited circumstances as described in § 207.81(c). FDA has found that nondisclosure of most drug listing information for marketed drugs would be inconsistent with the protection of the public health. In most cases, drug listing information is obvious or is disclosed elsewhere (*e.g.,* a drug's established and proprietary names, its dosage form and route of administration, its active ingredient(s)). Specifically, FDA has made a finding that nondisclosure of the listing information identified in the following bulleted list would be inconsistent with protection of the public health, except in limited circumstances as described in § 207.81(c):

- Information obtained under § 207.33 will be available for public disclosure, but only after a drug is marketed. This information that will be available for public disclosure includes information a registrant or private label distributor submits or updates under § 207.33(c) to obtain an NDC labeler code but does not include information submitted under § 207.33(d)(3) to reserve an NDC. Information submitted under § 207.33(c) to obtain a labeler code (and updates to the information) includes basic contact information for the registrant or private label distributor to whom the labeler code is assigned, the types of activities (*e.g.,* manufacture, repackaging, or private label distribution) in which the person requesting the labeler code engages with respect to drugs, and the types of drugs to which the labeler code will be applied. This is not necessarily, but is arguably, classified as drug listing information because it relates to NDCs and labeler code segments of NDCs. FDA makes the finding referred to in section 510(f) of the FD&C Act that nondisclosure of this information, in the case of marketed drugs, would be inconsistent with protection of the public health. The contact information described in § 207.33(c)(1)(i) allows consumers to verify in some cases that they do not have a counterfeit product. It also provides additional contact information for the consumer's reference. Disclosure of the types of activities reported under § 207.33(c)(1)(ii) may provide additional clarity as to a labeler's role in producing or marketing a drug. Information on the types of drugs to which a labeler code will be applied, described in § 207.33(c)(1)(iii), is largely available to the public, but centralizing it promotes the free flow of information to interested consumers.
- Most information obtained under § 207.49 (listing information a registrant must submit for a drug it manufactures) will be available for public disclosure after a drug is marketed. This information includes the drug's NDC; its established and proprietary name; the name and quantity of each active pharmaceutical ingredient in the drug; the name of each inactive ingredient (unless a valid assertion of confidentiality is made); the dosage form; the drug's approved U.S. application number if any; the drug type (finished vs. unfinished, human vs. animal, prescription vs. nonprescription); for drugs subject to the imprinting requirements of 21 CFR part 206, the drug's size, shape, color, scoring, and code imprint (if any); the route or routes of administration of the drug; the schedule of the drug under the Controlled Substances Act; advertisements; labeling; contact information for private label distributors; OTC monograph references if any; and the date on which a drug was introduced into commercial distribution. FDA makes the finding referred to in section 510(f) of the FD&C Act that nondisclosure of the foregoing information, in the case of marketed drugs, would be inconsistent with protection of the public health. The drug information described in §§ 207.49(a)(1), (3), (10), (15), and 207.49(b)(1) and (2) will enable individuals with concerns about counterfeiting to compare information about a product in their possession with information provided to FDA. The ingredient information described in §§ 207.49(a)(4) and (5) will in some cases allow individuals to verify ingredient information provided in labeling against FDA's records. The information described in §§ 207.49(a)(6), (8), and (11) relates to proper physical form and use of a drug. The application number described in § 207.49(a)(7) allows individuals to access disclosable FDA records about a drug's approval. Whether and how a drug is scheduled under the Controlled Substances Act (§ 207.49(a)(13)) relates to safe use of the drug. The advertisements and labeling described in §§ 207.49(a)(14) and (15) may include information individuals have not seen elsewhere describing the risks and benefits of a drug. Furthermore, FDA's disclosure of labeling information obtained under § 207.49(a)(15) will allow for the availability of current drug labeling information through DailyMed, a computerized repository of drug information maintained by the National Library of Medicine. The contact information described in § 207.49(a)(16)(ii) may provide additional contact information for an

individual's reference. All of this information is largely available to the public, but centralizing it promotes the free flow of information to interested consumers, health care providers, and others. Note that two types of information obtained under § 207.49 will not be available for public disclosure: (1) The names of inactive ingredients in a listed drug if the registrant listing the drug makes a valid assertion of confidentiality for them at the time of drug listing and (2) the number assigned to the Drug Master File or Veterinary Master File, if any, that describes the manufacture of an unfinished drug.

- Most information obtained under § 207.53 (listing information a registrant must submit for a drug that it repacks or relabels) will be available for public disclosure after a drug is marketed. This information includes the repacked or relabeled drug's NDC, labeling, advertisements, and contact information for private label distributors. FDA makes the finding referred to in section 510(f) of the FD&C Act that nondisclosure of the foregoing information, in the case of marketed drugs, would be inconsistent with protection of the public health. The NDC described in § 207.53(a) helps identify who repacked or relabeled a drug. Labeling and advertising information described in §§ 207.53(d) and 207.53(e) may include information individuals have not seen elsewhere describing the risks and benefits of a drug. Furthermore, FDA's disclosure of labeling information obtained under § 207.53(d) will allow for the availability of current drug labeling information through DailyMed, a computerized repository of drug information maintained by the National Library of Medicine. The contact information for private label distributors described in § 207.53(f)(2) may provide additional contact information for an individual's reference. All of this information is largely available to the public, but centralizing it will promote the free flow of information. Note that two types of information obtained under § 207.53 are not available for disclosure: (1) The NDC assigned to a finished drug received by a registrant for repacking or relabeling and (2) the name and UFI of establishments where repacking or relabeling is performed.
- Some information obtained under § 207.54 (listing information a registrant must submit for a drug it salvages) will be available for public disclosure after a drug is marketed. This information includes the salvaged drug's lot number and expiration date. FDA makes the finding referred to in section 510(f) of the FD&C Act that nondisclosure of the foregoing information, in the case of marketed drugs, would be inconsistent with protection of the public health. Disclosure of the lot number and expiration date information described in § 207.54(b) may help address any concerns about a salvaged product's quality, potency, and shelf life.
- Most information obtained under § 207.57 (information registrants must submit when updating listing information) will be available for public disclosure. In most cases, information submitted under § 207.57 updates information previously submitted under §§ 207.49, 207.53, or 207.54. The same disclosure rules will apply whether information is submitted in an original drug listing submission or in an updated listing. Our findings under section 510(f) of the FD&C Act, described previously, that nondisclosure of certain listing information obtained under §§ 207.49, 207.53, and 207.54 would be inconsistent with protection of the public health apply whether the information is obtained in an original listing submission or an updated listing submission. Accordingly, the reasons supporting this finding discussed previously apply to updates submitted under § 207.57. Some information obtained under § 207.57 will not have been received previously under §§ 207.49, 207.53, or 207.54. This information includes: (1) The date a registrant discontinues the manufacture, repacking, relabeling, or salvaging for commercial distribution of a listed drug and the expiration date of the last lot manufactured, repacked, relabeled, or salvaged, (2) the date a registrant resumes the manufacture, repacking, or relabeling, for commercial distribution or a drug previously discontinued, and (3) certifications that no changes have occurred since the last listing review and update. FDA makes the finding referred to in section 510(f) of the FD&C Act that nondisclosure of the foregoing information, in the case of marketed or discontinued drugs, would be inconsistent with protection of the public health. The date a business discontinues or resumes manufacturing a drug, submitted under § 207.57(b)(1)(ii) or (iii), may help address concerns some individuals may have about whether a drug in their possession is counterfeit. The certification that no changes have occurred described in § 207.57(b)(2) will inform individuals that drug listing information previously submitted to FDA is up to date as of the no changes certification date.

(Comment 86) One comment requested that FDA not disclose the names of inactive ingredients in animal drugs submitted with drug listing information. This comment stated that inactive ingredients in animal drugs are generally not listed on labels. Another comment urged FDA not to place the burden on registrants to proactively request that the names of inactive ingredients in human drugs be treated as trade secrets.

(Response) The proposed rule included a discussion about disclosure of inactive ingredients reported in drug listing submissions and stated that FDA will disclose this information unless it is subject to trade secret protection. See 71 FR 51276 at 51321. In this final rule, we are codifying that approach by making it clear in § 207.81 that we will not disclose the names of any inactive ingredients submitted with drug listing information for which the registrant makes a valid assertion of confidentiality under § 20.61 or other applicable provision of law.

This approach will apply to both human and animal drugs in an ingredient-specific way. In other words, in the absence of a well-supported assertion of confidentiality for any given inactive ingredient reported under § 207.49, the name of that inactive ingredient will be available for public disclosure. The inactive ingredient composition of a drug product is of interest to consumers and in most cases is already disclosed on drug labels. We find that categorical nondisclosure of inactive ingredient information would be inconsistent with protection of the public health. It is therefore appropriate that FDA consider this information disclosable in the absence of a valid assertion of confidentiality that supports nondisclosure.

(Comment 87) One comment urged FDA not to disclose the relationship between customs brokers and their clients. This comment noted that the proposed rule would have required foreign establishments to identify in their establishment registrations each person who imports or offers for import their drugs into the United States. The proposed rule would have defined the term "person who imports or offers for import" broadly to include agents and brokers. As with establishment registration information generally, this information would have been available for disclosure under § 207.81 of the proposed rule.

(Response) As explained in our response to comment 11, in this final rule, we define the term "person who imports or offers for import" more narrowly than it was defined in the proposed rule. The new definition is not intended to include persons operating merely as customs brokers. Therefore, a person operating merely as a customs broker will not be identified in a foreign establishment's registration information and hence will not have its relationship with the foreign establishment disclosed under § 207.81.

(Comment 88) One comment asked FDA to clarify the confidentiality of information submitted to obtain an NDC. Several comments stated that disclosure of listing information is inappropriate for a yet-to-be approved product.

(Response) As discussed in response to comment 31, under this final rule, registrants will propose their own NDCs with drug listing submissions. It is not necessary under this final rule to request an NDC from FDA and support that request with the information specified in § 207.33(c) of the proposed rule. Some of the information specified in proposed § 207.33(c) (*e.g.*, the drug's proprietary name and established name) has been added to drug listing information required under §§ 207.49, 207.53, and 207.54 of this final rule. The foregoing discussion explains which drug listing information will be available for disclosure and that it will not be available for disclosure until after the drug is marketed.

Section 207.33(d)(3) of this final rule allows anyone with a labeler code to voluntarily reserve an NDC for a drug product under development before it is listed. Information submitted under § 207.33(d)(3) to reserve an NDC is identified in § 207.81(b)(3) as generally exempt from disclosure. Because information submitted to FDA under § 207.33(d)(3) will relate to drug products under development, this exemption from disclosure prior to marketing is not inconsistent with protection of the public health.

(Comment 89) Two comments stated that under the proposed rule, drug listing information would be exempt from public disclosure unless the Secretary deemed its release to be necessary. These comments asked FDA to clarify the circumstances under which disclosure of drug listing information would be considered necessary.

(Response) These comments reflect a misunderstanding of the proposed rule. In the proposed rule, § 207.81 stated unambiguously that "[a]fter a drug is listed, all information obtained for that drug under §§ 207.33, 207.49, 207.53, and 207.54," except for stated exceptions, would be made available for public disclosure upon request or at FDA's discretion (71 FR 51276 at 51353). We have determined, under section 510(f) of the FD&C Act and as explained in the foregoing discussion, that most drug listing information relating to marketed products will be categorically presumed to be available for public disclosure because an exemption from disclosure would be inconsistent with protection of the public health. In the foregoing discussion, we have explained that § 207.81 of this final rule identifies a set of drug listing information that will generally not be available for public disclosure.

(Comment 90) One comment urged FDA not to disclose registration and listing information that reveals business relationships among trading partners, such as those between a drug's manufacturer and a private label distributor or between a manufacturer and a retail service repackager.

(Response) We have carefully considered this comment, along with section 510(f) of the FD&C Act and our longstanding rules and policies regarding disclosure of registration and listing information. As a statutory matter, establishment registration information is generally disclosable. (See section 510(f) of the FD&C Act.) Thus, information required for establishment registration under § 207.25 of this final rule is disclosable.

This final rule requires that foreign establishments report the name of each importer known to the establishment and the name of each person who imports or offers to import its drugs into the United States. This information is treated as establishment registration information under section 510(i) of the FD&C Act and under § 207.25 of this final rule, rather than as drug listing information. Because the information is establishment registration information, both the FD&C Act and this final rule require that it be available for public disclosure. FDA's intention to make this information available for disclosure was highlighted in the proposed rule (71 FR 51276 at 51321).

Drug listing information will not be available for public disclosure under this final rule unless its nondisclosure would be inconsistent with protection of the public health, as set forth in section 510(f) of the FD&C Act. Most drug listing information is obvious or is disclosed elsewhere such as in labeling (*e.g.*, size, shape, color, scoring, route of administration, approved application number, active ingredient(s)) and its nondisclosure would be inconsistent with protection of the public health. However, we recognize that, as emphasized in this comment, some drug listing information may reveal confidential business relationships. This final rule exempts from public disclosure drug listing information obtained under § 207.49(a)(12) (name and UFI of the establishments where a drug is manufactured and/or immediate source NDCs), § 207.53(c) (name and UFI of establishments where repacking or relabeling is performed), or § 207.54(c) (name and UFI of establishments where salvaging is performed).

(Comment 91) One comment urged FDA to treat all registration and listing information as categorically exempt from disclosure.

(Response) We decline to take this approach. As explained in the foregoing discussion, the disclosure provisions in this final rule are consistent with section 510(f) of the FD&C Act, notably its requirement that establishment registration information be made publicly available and that drug listing information be disclosed only to the extent that its nondisclosure would be inconsistent with protection of the public health.

H. Human Cells, Tissues, and Cellular and Tissue-Based Products (Part 1271)

The proposed rule included relatively minor amendments to part 1271 to require electronic submission of establishment registration and listing information for HCT/Ps. These amendments are retained in this final rule with some revisions. Under this final rule, manufacturers of HCT/Ps that are regulated solely under section 361 of the PHS Act are subject to establishment registration and listing under part 1271. Manufacturers of HCT/Ps that are regulated under section 351 of the PHS Act or as drugs under section 505 of the FD&C Act are subject to establishment registration and listing under part 207. (HCT/Ps that are regulated as medical devices under the FD&C Act are subject to establishment registration and listing under part 807.)

(Comment 92) One comment was concerned about the breadth of the definition of "importer" in proposed § 1271.3(mm). This comment noted that the proposed rule's definition of "importer" appeared to include domestic transplant centers (hospitals) housing patients awaiting hematopoietic stem cell (HSC) transplant and argued that requiring foreign establishments to identify such hospitals as "importers" would be unreasonably burdensome.

(Response) Please see our response to Comment 9 regarding the definition of "importer" in § 207.1. We agree with those comments that challenged the proposed definition as too broad, particularly as it would have captured downstream recipients of imported products. In parts 207, 607, and 1271, we have narrowed the new definitions of "importer" by adding the words "at the time of entry." Therefore, these definitions no longer capture downstream recipients such as hospitals.

IV. Compliance Dates

This final rule is effective November 29, 2016.

The proposed rule included proposed compliance dates by which registrants and other affected persons would be required to comply with different aspects of a final rule. For example, we proposed that manufacturers, repackers, and relabelers be given 3 years from the effective date of a final rule to ensure that the appropriate NDC appear on their labels. Proposed compliance deadlines were set forth in the preamble to the proposed rule but were not reflected in proposed codified regulatory language. (See 71 FR 51276 at 51345.)

The compliance dates are adjusted in this final rule to account for changes we have made in the final rule and to account for our 2009 implementation of electronic registration and listing under part 207 in accordance with revisions to the FD&C Act. Compliance dates associated with this final rule are presented in table 2.

Registrants are encouraged to comply with this final rule as soon as possible after its effective date. In many cases, the final rule will not necessitate changes in a registrant's current registration and listing practices because electronic submission of registration and listing information already takes place, and the information currently collected generally comports with this final rule. We recognize, however, that this final rule introduces new requirements, and some registrants will need to adjust their registration and listing activities. Table 2 should be read as a statement that FDA intends to exercise enforcement discretion between the effective date of this final rule and the compliance deadlines set forth in the table with respect to changes introduced in this final rule. At all times, however, persons subject to registration and listing must fulfill their statutory obligations and the relevant regulatory provisions set forth in parts 207, 607, and 1271, either before or after the effective date of this final rule.

TABLE 2—COMPLIANCE DEADLINES

Requirement	Effective date or compliance deadline
Effective date of the final rule	90 days after publication.
Electronic submission of establishment registration and listing information under amended part 207.	For products currently subject to part 207, the electronic submission requirement in section 510(p) of the FD&C Act was largely implemented through FDA's 2009 electronic registration and listing guidance (74 FR 26248). Upon the effective date of this final rule, FDA expects continued electronic submission of registration and listing information in accordance with our electronic registration and listing guidance and with new § 207.61. This applies to newly submitted registration and listing information as well as updates to information previously submitted. FDA will accept waiver requests in accordance with § 207.65 of this final rule upon its effective date. Two years after the effective date of this final rule, FDA intends to remove from our current electronic database establishment registration and listing information submitted in the past on paper and not updated with a more recent electronic submission. The purpose of this removal is to purge outdated information from our database, such as information registrants failed to update after discontinuing a drug product or closing an establishment. Therefore, registrants must migrate their establishment registration and listing information to our electronic system (or obtain a waiver from the electronic submission requirement) before that time if they have not already done so. Registrants may not rely on a "no changes" certification to migrate information submitted in the past on paper to our electronic system. They must enter and transmit current registration and listing information to FDA electronically.
Electronic submission of blood establishment registration and listing information under amended part 607.	Owners or operators of human blood product establishments currently register and list either electronically or by submitting Form FDA 2830 by mail. FDA will stop accepting paper submissions and require electronic submission of establishment registration and product listing information under amended part 607, unless individual waivers are granted, 1 year after the effective date of this final rule.
Electronic submission of HCT/P establishment registration and listing information under part 1271.	Owners or operators of HCT/P establishments currently register and list either electronically or by submitting Form FDA 3356 by mail. FDA will stop accepting paper submissions and require electronic submission of establishment registration and product listing information under amended part 1271, unless individual waivers are granted, 1 year after the effective date of this final rule.
Part 207, Subpart B—Registration (timing of establishment registration and update submissions and substance of the information submitted).	Registrants are required to submit and update establishment registration information in accordance with amended subpart B of part 207 no later than the time when registration information is due after the first anniversary of the effective date of this final rule. If the effective date falls between October 1 and December 31, registrants must submit information required by amended subpart B no later than the next October through December annual review and update period. However, registrants must comply with new § 207.29(a) (expedited updates when certain establishment registration information changes) upon the effective date of this final rule.

TABLE 2—COMPLIANCE DEADLINES—Continued

Requirement	Effective date or compliance deadline
Part 207, Subpart D—Listing (timing of drug listing and update submissions and substance of the information submitted).	Registrants are required to submit and update drug listing information in accordance with amended subpart D of part 207 (including the submission of NDCs that are formatted in accordance with subpart C of part 207) no later than the time when listing information is due after the first anniversary of the effective date of this final rule. If the effective date falls during either June or December, registrants must submit information required by subpart D no later than the June or December listing update 12 months after the effective date.
Part 607—Establishment registration for blood and blood products	Registrants are required to submit and update establishment registration information in accordance with amended part 607 no later than the time when establishment registration information is due after the first anniversary of the effective date of this final rule. If the effective date falls between October 1 and December 31, registrants must submit establishment registration information required by amended part 607 no later than the next October through December annual review and update period. However, registrants must comply with new § 607.26 (amendments to establishment registration for certain changes such as ownership or location) upon the effective date of this final rule.
Part 607—Listing for blood and blood products	Registrants are required to submit and update product listing information in accordance with amended part 607 no later than the time when listing information is due after the first anniversary of the effective date of this final rule. If the effective date falls during either June or December, registrants must submit information required by subpart D no later than the June or December listing update 12 months after the effective date.
Part 1271—Establishment registration for HCT/Ps	Registrants are required to submit and update establishment registration information in accordance with amended part 1271 no later than the time when registration information is due after the first anniversary of the effective date of this final rule. If the effective date falls in December, registrants must submit establishment registration information required by amended part 1271 no later than the next December annual review and update period under § 1271.21(b).
Part 1271—Product listing for HCT/Ps	Registrants are required to submit and update listing information in accordance with amended part 1271 no later than the time when listing information is due after the first anniversary of the effective date of this final rule. If the effective date falls during either June or December, registrants must submit information required by amended part 1271 no later than the June or December listing update 12 months after the effective date.

V. Legal Authority

We have the legal authority to amend our regulations on foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a BLA, and animal drugs. The statutory basis for our authority includes sections 201, 301, 501, 502, 503, 505, 506, 506A, 506B, 506C, 510, 512, 513–516, 518–520, 701, 704, 721, 801, and 903 of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 360, 360b, 360c–360f, 360h–360j, 371, 374, 379e, 381, and 393); 15 U.S.C. 1451–1561; sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264); and section 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

Section 510(c) of the FD&C Act requires every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug to immediately register with the Secretary his name, place of business, any such manufacturing establishments and their unique facility identifiers, and a point-of-contact email address. The provisions in section 510(b) and (d) of the FD&C Act require annual registration beginning on October 1 and ending on December 31 of each year and registration of additional establishments, respectively. Section 510(i) of the FD&C Act requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the Secretary by providing certain information. These provisions, together with section 701(a) of the FD&C Act (among others), authorize us to require the submission of the registration information specified in the final rule. The information specified in this final rule will help us identify who is manufacturing, repacking, relabeling, or salvaging drugs and where those operations are being performed. In addition, some information (*e.g.,* official contact information) will help us communicate with establishments more effectively and schedule inspections more efficiently.

Section 510(j)(1) of the FD&C Act requires every person who registers to file with the Secretary, at the time of registration, a list of all drugs that are being manufactured, prepared, propagated, compounded, or processed by the registrant for commercial distribution. That list must be prepared in the form and manner prescribed by the Secretary and must be accompanied by a copy of labeling (or the label and package insert) and, in some cases, advertising. Section 510(j)(2) of the FD&C Act requires listing information updates every June and December. This listing information gives us a current inventory of marketed drugs. These provisions of the FD&C Act and others, together with section 701(a) of the FD&C Act, provide authority for requiring the submission of listing information set forth in this proposal. The drug listing information specified in this final rule will help us: (1) Develop a more current, robust inventory of drugs as a counter-terrorism measure; (2) more effectively administer our postmarketing surveillance programs; (3) facilitate recalls of products; (4) identify drugs or ingredients in short supply in the event of a national emergency; and (5) identify drugs marketed in violation of the law.

Section 510(b) of the FD&C Act requires that information registrants supply for annual registration includes a UFI for the establishment and includes a point-of-contact email address. FDA published final guidance in November 2014 specifying that FDA's preferred UFI for drug establishment registration is the DUNS number, assigned and managed by Dun & Bradstreet.

Section 510(p) of the FD&C Act requires electronic submission of establishment registration and listing information, unless FDA waives the electronic submission requirement in individual cases. Establishments that manufacture HCT/Ps currently register and list HCT/Ps under FDA's regulations in part 1271. Pursuant to authority under section 361 of the PHS Act, FDA is requiring electronic submission of registration and listing information for HCT/Ps.

Section 510(j) requires biannual updates of certain listing information. Requiring certification under section 701(a) authority will help us with the efficient enforcement of the FD&C Act because we will be able to distinguish between situations where there has been noncompliance with registration and listing requirements from situations where there have been no changes in information. The failure to register or list under section 510 is a prohibited act under section 301(p) of the FD&C Act, and the failure to do either renders a drug misbranded under section 502(*o*) of the FD&C Act.

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final requirements will not impose a significant burden on a substantial number of small entities (annualized costs represent at most, 0.01 percent of sales for small firms, and 0.002 percent for large firms, on average), we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs

The full assessment of the economic analysis is available in Docket No. FDA–2005–N–0464 (Ref. 1) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

The final rule clarifies and codifies the Congressionally mandated requirements in FDAAA and FDASIA, and adds a few additional requirements to the information needed to list products. The final rule will improve management of the establishment registration and drug listing requirements and make these processes more efficient and effective for industry and for FDA. Maintaining a comprehensive electronic registration and listing system supports implementation of the electronic prescribing provisions of the MMA. Because registrants submit electronic copies of the drug labeling with their drug listing, this rule also ensures the availability of current drug information through DailyMed, a computerized repository of drug labeling maintained by the National Library of Medicine. Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Quickly accessible electronic information about each establishment in the supply chain will help inform our enforcement efforts and improve our oversight of the entire drug supply chain. Product listing information also gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Under current practices, registrants would only update listings when the listing information has changed. Consequently, some registrants have never submitted listings in an electronic format. By requiring electronic listings for all marketed drugs, the final rule will modernize our electronic systems and close an existing gap in data for drugs that are listed in our legacy system but not currently listed in our electronic system. Because the final rule primarily codifies current business practices, we anticipate that most of the benefits of a modern electronic drug registration and listing system were achieved as firms implemented electronic submissions in response to the FDAAA and FDASIA legislation. The incremental changes required by the final rule will yield benefits in addition to those already achieved. However, we lack sufficient information to quantify these marginal benefits.

Table 3 provides an itemized description of each incremental cost associated with registration and listing for part 207, part 607, and part 1271 registrants. For part 207 registrants, the final rule will require immediate source NDCs for unfinished drugs, listing missing inactive ingredients, and certification of no changes to their drug listings. Without the final rule, FDA faces an information gap because companies do not always notify the Agency when they stop marketing a product. For part 607 and part 1271 registrants, the requirements are quite slight for those that already submit registration and listing information electronically and minimal for the much smaller number of establishments that need to migrate their paper registration and listing records to electronic format. All registrants will incur costs associated with reading and understanding the rule and revising their standard operating procedures (SOPs), and these items represent the largest incremental cost. Most incremental costs are one-time only; the only recurring costs are for part 207 registrants for certifying no changes to their listings the previous year when they renew their registrations.

TABLE 3—ITEMIZED INCREMENTAL COSTS

[$ millions] [1]

Incremental costs	Frequency	Number of hours per unit	Number of units	Total cost
Drugs and biological products (part 207):				
Identify source of unfinished drugs (from source NDCs).	Once	0.25	93,700 listings	$3.1
Listing inactive ingredients	Once	0.25	40,800 listings	1.4
Listing legacy products	Once	2.5	26,300 listings	8.7
Read and understand the final rule	Once	21	5,900 registrants	16.5
Revise SOPs for registration and listing	Once	19	5,900 registrants	14.9
Revise SOPs for reusing NDCs	Once	11	2,950 registrants	4.3
Certification of no-change	Recurring annually	0.5	7,300 establishments	0.5
Total costs (part 207)				49.4
Human-blood products (part 607):				
Read and understand the final rule	Once	14	2,700 registrants	5.0
Revise SOPs for registration and listing	Once	11	27 registrants	0.04
Migrating records to FDA's electronic systems	Once	1	27 registrants	0.0
Total costs (part 607)				5.1
Human-cell and tissue products (part 1271):				
Read and understand the final rule	Once	14	2,800 registrants	5.2
Revise SOPs for registration and listing	Once	11	280 registrants	0.4
Migrating records to FDA's electronic system	Once	1	280 registrants	0.0
Total costs (part 1271)				5.7

[1] We considered the length of the final rule, the number of small and large firms affected, and the extent each firm is affected in order to estimate the burden to read and understand the rule. For part 607 registration and listing, the cost estimate shown as $0.0 million represents $3,591. For part 1271 registration and listing, the cost estimate shown as $0.0 million represents $37,240.

Table 4 summarizes the total incremental costs; total annualized costs are $9.0 million when calculated at a 7-percent discount rate over 10 years, or $7.5 million when calculated using a 3-percent discount rate.

TABLE 4—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

				Units			
Category	Primary estimate ($millions)	Low estimate ($millions)	High estimate ($millions)	Year dollars	Discount rate (percent)	Period covered (years)	Notes
Benefits:							
Annualized Monetized $ millions/year.					7		
					3		
Annualized Quantified					7		
					3		
Qualitative	The final rule will complete and codify modernization of the registration and listing system, thus allowing FDA to identify establishments, specific drugs or ingredients, to facilitate recalls or information alerts, and to exercise competent oversight of this important industry.						
Costs:							
Annualized Monetized $ millions/year.	$ 9.0			2014	7	10	Recurring costs include only annual time costs of certifying there are no changes to listings; these costs are unique to part 207 registrants.
	$ 7.5			2014	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							

TABLE 4—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT—Continued

				Units			
Category	Primary estimate ($millions)	Low estimate ($millions)	High estimate ($millions)	Year dollars	Discount rate (percent)	Period covered (years)	Notes
Federal Annualized Monetized $ millions/year.	....	....	....	....	7 3		
From/To	From:			To:			
Other Annualized Monetized $ millions/year.	....	....	....	....	7 3		
From/To	From:			To:			

Effects:

State, Local or Tribal Government: No estimated effect.

Small Business: The final rule will have little impact on small businesses; annualized costs represent, at most, 0.01 percent of annual sales for small firms and 0.002 percent for large firms, on average.

C. Response to Comments on the Preliminary Impact Analysis of the Proposed Rule

Most of the comments on the regulatory impact analysis of the proposed rule (PRIA) concerned the assignment of NDC numbers and the requirement that they be printed on container labels. Because these proposed changes are not included in the final rule, the comments are moot and are not discussed here. We also do not discuss the comments on the analysis of the proposed implementation of mandatory electronic registration and listing as this was mandated by FDAAA and largely implemented by guidance in 2009. Interested parties were able to comment on the burden estimates presented in the draft guidance entitled "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing" when it was announced in the **Federal Register** of July 11, 2008 (73 FR 39964) (available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs). The remaining comments have been grouped by topic; the order in which they are discussed is not a reflection of importance.

(Comment 93) Some manufacturers believed the PRIA did not address the financial impact on their sector of the industry and disagreed with the Agency's assertion of no significant economic impact on a substantial number of small businesses. In particular, manufacturers of medical foods and medical devices did not believe we properly addressed the loss of revenue they could experience if they could not use NDC numbers on their products. Contract manufacturers felt there should be a separate analysis of their sector of the industry as did medical gas firms who asserted their numbers were underrepresented.

(Response) We disagree with the comments. NDC numbers were never intended for use on medical foods. The medical food industry began using NDCs to simplify reimbursement payments by insurance companies. There are other mechanisms that can be used for medical food product reimbursement, and the secondary impact from FDA enforcement of existing rules is not part of a regulatory impact analysis of new requirements. The Unique Device Identification System final rule (78 FR 58786, September 24, 2013) replaces the use of NDC numbers on medical devices with a UDI number. The impact of this change was accounted for in that rule.

The PRIA measured the incremental cost to comply with the new or changed requirements on a per-establishment and per-listing basis. Most of the data in the analysis of the proposed rule are not relevant for the final rule because mandatory electronic submission began in June 2009 with the statutory implementation authorized by FDAAA; however, the methodology is relevant. We estimated the incremental cost for registration on a per establishment basis. We included all registered establishments in our estimate, so establishments in all industry sectors required to register are included in the analysis if they comply with the requirement. The information required for each establishment is essentially the same. Any economies of scale for a large firm to register multiple establishments at one time are economically insignificant. The same is true for the incremental cost to list products. A contract manufacturer, or a repackager, may have more than one product to list, but the information required for each product is essentially the same for a contract manufacture and other manufacturers. The final rule provides that a private label distributer can list the products it distributes on behalf of contract manufacturers, but the legal obligation remains the contract manufacturers'.

The Regulatory Flexibility Act requires Agencies to assess the regulatory impact on domestic small entities and to analyze options that would lessen the burden on small entities. The Small Business Administration defines a drug manufacturer as small if it employs fewer than 750 people and a biological products entity as small if it employs fewer than 500.

The size of the entity is determined by the total employment of the ultimate parent firm, which can include companies outside the drug and biological products industries. For example, if a drug manufacturer's ultimate parent is a financial holding company that employs more than 750 people across a variety of industrial and service sectors, the firm would be considered large even if employment in drug manufacturing is only 100 employees.

For the proposed rule, we used a crude method, using U.S. Census information and a database of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the Orange Book) to characterize the number and size of the affected firms and used U.S.

Census data from the 2002 Economic Census and County Business Patterns for the financial information in the regulatory flexibility analysis. The Census data are reported by North American Industry Classification System codes (NAICS). Depending on the survey, the economic data are collected on an establishment or firm level. Companies whose primary NAICS code is not a drug or biologic manufacturer would not be included in the financial survey data. For example, the primary NAICS code for many small medical gas companies is not pharmaceutical preparations manufacturing (NAICS 325412), so these establishments are not included in the Census data for NAICS 325412. Including the financial data for medical gas establishments in the analysis would be optimal, but we are not aware of publicly available data that would capture this information. Although the financial information characterizing the industry did not include the medical gas sector, medical gas establishments were included in the burden estimates.

The regulatory impact analysis for this final rule uses Dun & Bradstreet information on total employment of the ultimate parent company to determine the size of entities affected by the rule, but we still use the Census data for NAICS 325412 and 325414 for the financial information because of limitations of available data.

There were a number of comments regarding the burden of submitting certain information in listing, in particular batch information, inactive ingredients, and certifying that there has been no change to a listing.

(Comment 94) Some comments noted that batch information is already included in annual reports for products that require applications, so the information is a duplication of effort. These comments also noted that this information can change often and adds an additional element that needs to be tracked and updated.

(Response) After considering the comments, FDA has decided not to include the batch information requirement in the final rule.

(Comment 95) Some comments suggested FDA reconsider the requirement or frequency of the requirement to certify that no change is necessary for listings every June and December. Using the 0.25-hour estimate from the proposed rule for the time required to verify and certify a listing, one company with 800 products calculated that it would take 114 hours (around 14, 8-hour days) twice a year to comply with the requirement, assuming about 60 percent of their total products did not require updates in June and December. Another company with over 7,000 products said it would take 6 months to validate and certify their listings with no changes. They suggested making the no changes certification requirement every 2 years rather than biannually. Another comment suggested that changing the requirement to certifying by establishment, rather than by listing, would result in a savings of $1 million per year.

(Response) After considering the comments, we have revised the requirement for no changes certification from a per-listing basis to an establishment basis. Rather than certifying each June and December that there is no change to each individual listing, registrants can certify by establishment that the electronically listed products are up to date when they annually renew their registrations.

(Comment 96) Some comments regarding submitting inactive ingredients as part of listing stated it was unnecessary, burdensome, and in some cases would result in the release of information a company considered proprietary. These comments noted that inactive ingredients are included in human and animal drug applications and must be listed on the labels of OTC products. Some manufacturers of animal drugs claimed that inactive ingredients are not customarily supplied on the label and were concerned with the release of proprietary information.

(Response) Although inactive ingredients are identified in product applications and, in many cases, on product labels, the information is not easily accessible and the names are not fully standardized. Listing is the only mechanism by which FDA can readily access ingredient information across all products. Entering the inactive ingredients using defined terminology increases the accuracy and the efficiency of data searches. We use the information in listing to inform many processes FDA uses for protecting public health, including surveillance for serious drug adverse reactions, inspection of facilities used for drug manufacturing and processing, and monitoring drug products imported into the United States. To prevent public disclosure of information a registrant views as confidential, an inactive ingredient can be designated as confidential during the listing process.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.

Description: The final rule reorganizes, consolidates, clarifies, and modifies current regulations on registering establishments and listing drugs codified in part 207 for human and animal drugs, in part 607 for blood and blood products, and in part 1271 for HCT/Ps. The final rule describes when and how to register and list and what information must be submitted for registration and listing. The final rule clarifies the NDC system for drugs and requires that each drug product subject to the listing requirements of this final rule have a unique NDC.

The final rule codifies the current statutory requirement that registration and listing information be submitted to FDA electronically instead of using paper forms unless a waiver is obtained. Historically, drug establishment registration and drug listing information was submitted using Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). Before the enactment of FDAAA, section 510(p) of the FD&C Act expressly provided for electronic submission of drug establishment registration information upon a finding that electronic receipt was feasible, and section 510(j) of the FD&C Act specified that drug listing information was to be prepared in the form and manner prescribed by FDA. Section 224 of FDAAA, which amended section 510(p) of the FD&C Act, now requires electronic drug listing in addition to electronic drug establishment registration. In certain cases, and as discussed in section VIII.E, if it is unreasonable to expect a person to submit registration and listing information electronically, FDA may grant a waiver from the electronic submission requirement.

In June 2009, FDA made available the electronic registration and listing guidance (74 FR 26248, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) to provide recommendations on fulfilling the statutory requirement to submit electronically drug establishment registration and drug listing information. The guidance describes the types of information to include for purposes of drug establishment registration and drug listing and how to prepare and submit the information in an electronic format (Structured Product Labeling (SPL) files) that FDA can process, review, and archive. In June 2009, FDA began accepting submissions required under the part 207 regulations into our electronic drug registration and listing system. The format for these electronic submissions employs Extensible Markup Language (XML) and uses the SPL standard to organize the data within the file. This electronic registration and listing enables FDA to employ a number of automated validations to ensure the quality of the data received.

In addition to the information that previously was collected on the FDA forms, the electronic registration and listing guidance addresses, with respect to part 207, the electronic submission of other statutorily required information as follows:

- The name of each importer that is known to the establishment (the U.S. company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States) (section 510(i)(1)(A) of the FD&C Act);
- The name of each person who imports or offers the foreign establishment's drug for import (the name of each agent, broker, or other entity, other than a carrier, that the foreign drug establishment uses to facilitate the import of its drug into the United States) (section 510(i)(1)(A) of the FD&C Act); and
- For a registered foreign drug establishment, the name, address, and telephone number of its U.S. agent (§ 207.40(c)).

The electronic registration and listing guidance also recommends the voluntary submission of the following additional information, when applicable:

- The email address for the United States agent, and the telephone number(s) and email address for the importer and person who imports or offers for import their drug;
- A site-specific Data Universal Numbering System (DUNS) number for each entity (in November 2014, we issued the guidance for industry entitled "Specification of the Unique Facility Identifier System for Drug Establishment Registration" (79 FR 65977, available on the Internet at *http://www.fda.gov/Drugs* under Guidances (Drugs)) and obtained OMB approval to broaden the entity identification number covered in OMB control number 0910–0045);
- The NDC product code for the source drug that is repacked or relabeled;
- Distinctive characteristics of certain listed drugs (*i.e.,* the flavor, the color, and image of the actual solid dosage form); and
- Registrants may indicate that they view as confidential an inactive ingredient or the registrant's business relationship with an establishment.

We currently have OMB approval under the PRA (OMB control number 0910–0045) for the information collection in current part 207, the information that was submitted using Form FDA 2656, Form FDA 2657, and Form FDA 2658, and the information collection set forth in the electronic registration and listing guidance, including the electronic submission of registration and listing information as required by FDAAA. The information collection for current part 607 is approved by OMB under OMB control number 0910–0052. The information collection for current part 1271 is approved by OMB under OMB control number 0910–0543.

In tables 5, 6, 7, and 8, we estimate the total burden to comply with the applicable information collection requirements for parts 207, 607, and 1271 as set forth in this final rule. These burden estimates for the applicable regulations will replace some of the currently approved estimates in OMB control numbers 0910–0045, 0910–0052, and 0910–0543. These estimates are based on FDA's experience with reviewing registration and listing submissions under part 207 since June 2009 and on the number of submissions currently received, the number of respondents submitting this information, and the number of registered establishments and listed drugs, blood products, and HCT/Ps currently in FDA's drug registration and listing database.

A. Registration Information Collection Under Part 207

1. Requirements

Under § 207.17, manufacturers, repackers, relabelers, and drug product salvagers must register their establishments. This is consistent with current registration information collection, except that PET drug producers are not exempt from registration under the final rule, and the final rule states that FDA will accept registration information from a private label distributor if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Under § 207.21, domestic manufacturers, domestic repackers, domestic relabelers, and domestic drug product salvagers must complete initial registration of each establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug. In addition, foreign manufacturers, foreign repackers, foreign relabelers, and foreign drug product salvagers must register each establishment before the drug is imported or offered for import into the United States. This is consistent with current registration information collection.

The information that must be provided to FDA for registration is described in § 207.25. The final rule does not require the following currently required information collection:

- Kind of ownership or operation.
- Title of each corporate officer and director.

The final rule requires the following new registration information collection:

- Type of operations performed at each establishment.
- Contact information for the establishment's official contact.

Under § 207.29, registrants must review their registration information annually between October 1 and December 31and report all changes to their registration information or certify that no changes have occurred. In addition to the annual review and update, registrants must submit expedited reports of certain changes within 30 calendar days of the change. Currently, registrants must renew their registration information annually and submit certain amendments to registration within 5 days of a change. Section 207.29 differs from the current requirement to submit amendments to registration in the following ways:

- The final rule lengthens the current time period for reporting changes to registration information from 5 days (10 business days for a change in United States agent information) to 30 calendar days.
- The final rule revokes the current requirement to report a change in individual ownership and corporate or partnership structure and the current requirement to submit a signed

statement for a change in a registered establishment's firm name.

New registration information collected under the final rule includes the certification that no changes have occurred and reporting certain changes as expedited updates within 30 calendar days.

2. Burden Estimates

Based on the number of new establishments that currently register each year, we estimate that approximately 1,400 registrants will submit electronically approximately 2,800 new establishment registrations annually. Based on the number of registered establishments in our database, we estimate that approximately 10,000 registrants will provide approximately 10,000 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred.

The estimates include the registration of establishments for both domestic and foreign manufacturers, repackers, relabelers, and drug product salvagers, and registration information submitted by anyone acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs. The estimates include an additional 80 PET drug producers who are not exempt from registration under the final rule and approximately 30 manufacturers of plasma derivatives.

We estimate that it will take approximately 1 hour for registrants to submit initial registration information electronically for each new establishment.

We also estimate that it will take approximately 30 minutes for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred.

The burden hour estimates are based on our familiarity with the amount of time it takes registrants to input registration information electronically since June 2009. The estimates are an average of the time it would take to register a domestic or foreign establishment and an average of the time it would take to review registration information and update several registration items in the database or review registration information and only certify that no changes have occurred.

B. Listing Information Collection Under Part 207

1. Requirements

Under § 207.41, registrants must list drugs they manufacture, repack, relabel, or salvage for commercial distribution. This requirement is consistent with current listing information collection, except that drug product salvagers are not currently required to list under part 207.

The final rule revises current NDC-related listing submissions as follows:

- A registrant must list each drug it manufactures, repacks, or relabels using an NDC that includes the registrant's own labeler code, regardless of whether the drug is commercially distributed under the registrant's own label or trade name or under the label or trade name of a private label distributor.
- Each registrant must list each drug it manufactures, repacks, or relabels for commercial distribution under the trade name or label of a private label distributor using an NDC that includes such private label distributor's labeler code.
- During listing, each manufacturer, repacker, or relabeler must propose for assignment by FDA an NDC that includes its own labeler code for each package size and type of drug that it manufactures, repacks, or relabels for commercial distribution.
- If a drug is distributed under the trade name or label of a private label distributor, the manufacturer, repacker, or relabeler must also propose for assignment by FDA an NDC that includes the labeler code of the private label distributor under whose trade name or label the drug is distributed, for each package size and type so distributed.
- A manufacturer, repacker, relabeler, or private label distributor may also reserve a proposed NDC for a drug, before the drug is listed, by submitting certain information.

Under § 207.45, registrants must list, no later than 3 calendar days after the initial registration of each establishment, any drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at that establishment. This requirement is consistent with current listing information collection, except that the final rule specifies within 3 calendar days after initial registration.

Under the final rule, the information registrants must submit to list a drug, including the information that must be submitted (by a registrant or a private label distributor) to receive a labeler code, is described in §§ 207.33, 207.49, 207.53, 207.54, 207.55, and 207.61. Under current part 207, we assign a labeler code to each registrant and the registrant assigns the product code and the package code for each drug product's NDC.

The listing and NDC information collections required by the final rule are already approved by OMB under OMB control number 0910–0045, except for the following: (1) The name of each inactive ingredient in a listed drug (assertions of confidentiality associated with individual inactive ingredients are covered in the electronic registration and listing guidance); (2) additional information, such as email address, to identify a domestic registrant (identifying information for foreign registrants is part of the electronic registration and listing guidance information collection and in current § 207.40(c)); (3) the drug master file or veterinary master file number, if one exists, must be submitted by the manufacturer for an unfinished drug; (4) drug product salvagers (who do not repack or relabel) must submit the lot number and expiration date and NDC assigned to the drug immediately before the drug is received by the drug product salvager; (5) all new labeling for a repacked or relabeled drug must be submitted, and not only the changed labeling; (6) package type and volume information corresponding to the package code segment of the NDC must be submitted; (7) a drug's OTC monograph reference (if any) and the date on which the drug was or will be introduced into commercial distribution are both requested for voluntary submission; and (8) the name and Unique Facility Identifier (UFI) of the establishment where the registrant who lists the drug manufactures it and the type of operation performed on the drug at that establishment, and, if an immediate source NDC is not provided, the name and UFI of every other establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment must be provided.

Under § 207.57, registrants must update drug listing information submitted previously (either when the change is made or, at a minimum, each June and December). Registrants must also notify FDA if any listed drug has been discontinued from marketing or if any discontinued drug has been reintroduced and provide listing information for any drug not yet listed (at the time of annual establishment registration if not sooner). Under § 207.35, registrants must notify us of a change in any of the drug characteristics (except certain identifying information) for an NDC in § 207.33, and assign a new product code and package code for that drug. Current listing information collection does not specifically require any type of certification if there are no changes, and only material changes to listing information must be reported.

2. Burden Estimates

Based on the number of drugs listed annually since June 2009, we estimate that approximately 1,713 registrants will submit electronically approximately 12,469 new listings annually (including the information submitted to obtain a labeler code and to reserve an NDC for future use).

Based on the number of drugs in our listing database and the current number of changes to listing information submitted, we estimate that approximately 5,300 registrants will provide approximately 10,000 June and 10,000 December reviews and updates of listing information—a total of approximately 20,000 submissions annually (including the information submitted to revise an NDC).

The estimates for the number of drug listings include both domestic and foreign listings, listings submitted by registrants for products sold under their own names as well as products intended for private label distribution, and information submitted related to an NDC and to obtain a labeler code. The estimate for the number of drugs subject to the listing requirements includes PET drugs and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information include the number of changes to drug characteristics pertaining to the drug product code to obtain a new NDC and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

Based on our familiarity with the time required to input listing information electronically since June 2009, we estimate that it will take registrants approximately 1 hour and 30 minutes to submit information electronically for each drug they list for the first time (for both foreign and domestic registrant listings). These estimates are an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers, with drug product salvagers taking considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in electronic format. (For drugs subject to an approved marketing application, the electronic submission of the content of labeling under current § 314.50(l)(1)(i) is also approved under OMB control number 0910–0001.) We also estimate that it will take approximately 45 minutes for each June and December review and update of listing information. These estimates are an average of the time it would take to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC, and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

C. Registration and Listing Information Collection Under Part 607

1. Requirements

Under § 607.22(a) of the final rule, blood establishments must submit initial and subsequent registration and product listing electronically through the Blood Establishment Registration and Product Listing system, or any future superseding electronic system. All information submitted under this part must be transmitted to FDA electronically. Currently, under § 607.22, manufacturers must register establishments and list blood products on Form FDA 2830. The requested information is consistent with the current requirement to register establishments and list products approved under OMB control number 0910–0052. A separate discussion regarding waivers under § 607.22(b) is discussed in section E.

Under §§ 607.25(a) and 607.25 (b)(3) of the final rule, establishments must include the Unique Facility Identifier as part of the registration and product listing. The other requested information under this regulation is consistent with the current requirements to register establishments and list products approved under OMB control number 0910–0052.

Under § 607.25(b)(1) of the final rule, blood establishments are required to list blood products by the established and proprietary name. This is consistent with the current listing requirement approved under OMB control number 0910–0052. Currently, manufacturers of plasma derivatives and bulk product substances register and list under both parts 607 and 207. The final rule revises this requirement by requiring persons who engage solely in the production of plasma derivatives, bulk product substances, and recombinant version of plasma derivatives or animal derived plasma derivatives to register and list only under part 207. Any reduction in burden is expected to be minimal (approximately 20 establishments) and will be reflected under OMB control number 0910–0052. To be consistent with part 207, we are also deleting the reference in part 607 to Form FDA 2250 (National Drug Code Directory Input) because this form is no longer being used by CDER or CBER.

Under current § 607.40, foreign establishments must include information for the United States agent as part of its initial and updated registration. The final rule requires submission of minimal additional information (*i.e.*, email address) for the United States agent. This information is consistent with the current registration information approved under OMB control number 0910–0052. The final rule requires the foreign establishment to report to FDA changes in the United States agent's name, address, telephone number, and email address within 30 calendar days of the change. The final rule lengthens from 10 business days to 30 calendar days the time period for reporting changes in the United States agent's information to FDA.

2. Burden Estimates

Based on the number of new establishments that currently register with FDA each year, we estimate 68 establishments will provide new establishment registration and product listings annually under §§ 607.22(a), 607.25(a), and (b)(3).

We estimate that it takes approximately 60 minutes to provide the initial registration and listing information for each new establishment.

Based on the number of establishments that currently submit registration and product listing updates, we estimate 2,615 establishments will provide establishment registration and product listing updates annually under §§ 607.22(a), 607.25(a), and (b)(3).

We estimate that it takes approximately 30 minutes to provide the establishment registration and listing update information for establishment.

These burden hour estimates are based on institutional experience with the current registration and listing requirements.

D. Registration and Listing Information Collection Under Part 1271

1. Requirements

Under § 1271.22, establishments must register, list products, and provide updates electronically. The current regulation includes the option to submit registration, listing, and updates electronically.

Under § 1271.25, establishments must also submit the telephone number and email address of the reporting official. Each foreign establishment must submit the name, the address, telephone number, and email address of each importer that is known to the establishment and the name of each person who imports or offers for import such HCT/P to the United States. Foreign establishments must also submit the name, the address, telephone number, and email address of their United States agent.

Under § 1271.26, establishments must report a change to the United States agent's name, address, telephone number, or email address. The final rule will also lengthen to 30 calendar days the current requirement of reporting the changes within 5 days.

2. Burden Estimates

Based on the number of new establishments that currently register with FDA each year, we estimate that approximately 225 establishments will provide new establishment registration annually. Based on information from FDA's database, we estimate that approximately 2,700 establishments are registered and listed with FDA and will provide establishment and listing updates. The number of establishments that currently register and list with FDA includes both foreign and domestic establishments. If no change has occurred, an update is not required. Based on the number of establishments from FDA's database, we estimate that approximately 1,200 establishments will provide changes to establishment ownership or location, or changes to the United States agent's information.

We estimate that it would take approximately 45 minutes to provide the initial registration and listing information for each new establishment.

We estimate that it would take approximately 30 minutes for each annual review and update of registration and listing information for each establishment.

We estimate that it would take approximately 15 minutes for each establishment to provide a change in ownership and location, or a change to the U.S. agent's information.

These burden hour estimates are based on institutional experience with the current registration and listing requirements. The estimates are an average of the time it would take to register an establishment, and an average of the time it would take to review registration and listing information, and update several registration and listing items in the database.

E. Waiver Request Information

1. Part 207

Under § 207.65, registrants may request a waiver from the requirement in § 207.61 that information must be provided to us in electronic format. We expect very few waiver requests because only a computer, Internet access, and an email address are needed to register and list electronically and because electronic submission has been required since June 2009.

We estimate that approximately one registrant will request a waiver annually and that each request will take approximately 30 minutes to prepare and submit to us.

2. Part 607

Under § 607.22(b), both domestic and foreign establishments may request a waiver from the requirement that information must be provided to FDA in electronic format. We expect few waiver requests because only a computer, Internet access, and an email address are needed to register and list electronically.

We estimate that approximately 25 manufacturers will request a waiver annually and that each request will take approximately 1 hour to prepare and submit to us.

When we grant a request for a waiver, we intend to make available to the manufacturer the paper form—Form FDA 2830 for registration and listing.

3. Part 1271

Under § 1271.23, manufacturers may request a waiver from the requirement in § 1271.22 that information must be provided to FDA in electronic format. We expect a limited number of waiver requests because only a computer, Internet access, and an email address are needed to register and list electronically.

We estimate that approximately 100 manufacturers will request a waiver annually and that each request will take approximately 1 hour to prepare and submit to FDA.

When we grant a request for a waiver, we intend to make available to the manufacturer the paper form—revised Form FDA 3356 for registration and listing.

F. Public Disclosure Exemption Requests

Under § 207.81(c), registrants may request that certain information in § 207.81(a) not be made available from their registration and listing information. Based on our experience with registration and listing information inspection requests under current § 207.37, we estimate that approximately 100 registrants will submit this request annually and that each request will take approximately 1 hour to prepare and submit to us. (Assertions of confidentiality associated with individual inactive ingredients or the registrant's business relationship with an establishment is part of the June 2009 electronic registration and listing guidance information collection and is covered under OMB control number 0910–0045).

G. Standard Operating Procedure for Electronic Submission

The requirement under section 510(p) of the FD&C Act for electronic drug establishment registration and electronic drug listing resulted in our amending OMB control number 0910–0045 in June 2009 to include the burden for preparing a standard operating procedure (SOP) for the electronic submission requirement, creating the SPL file, including accessing and reviewing the technical specifications and instructional documents provided by FDA, reviewing and selecting appropriate terms and codes used to create the SPL file, obtaining the digital certificate used with FDA's electronic submission gateway, and uploading the SPL file for submission. Although most registrants have already prepared an SOP for the electronic submission requirements, each year additional firms will need to create an SOP. As provided in table 6, FDA estimates that approximately 1,000 firms will have to expend a one-time burden to prepare, review, and approve an SOP, and we estimate that it will take approximately 40 hours per recordkeeper to create 1,000 new SOPs, for a total of 40,000 hours. We also estimate approximately 3,295 hours for annual recordkeeping maintenance of these records.

H. Capital Costs

There are one-time capital costs associated with this rulemaking. These costs are discussed in section VII, "Economic Analysis of Impacts."

Description of Respondents: Manufacturers, repackers, relabelers, drug product salvagers, and private label distributors as described in the final rule.

Burden Estimate: Tables 5, 6, 7, and 8 provide the annual reporting and recordkeeping burdens for this final rule.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN UNDER PART 207

21 CFR Sections and reporting requirements	Number of respondents	Number of responses per respondent	Total annual responses	Hours per registration or listing	Total hours
Initial Establishment Registration (§§ 207.17, 207.21, 207.25)	1,400	2	2,800	1	2,800
Annual Review and Update of Registration Information (including expedited updates) (§ 207.29)	10,000	1	10,000	0.50	5,000
Initial Listing (including NDC) Information (§§ 207.33, 207.41, 207.45, 207.49, 207.53, 207.54, 207.55)	1,713	7.28	12,470	1.5	18,705
June and December Review and Update (or Certification) of Listing (including NDC) Information (§§ 207.35, 207.57)	5,300	20	106,000	0.75	79,500
Waiver requests (§ 207.65)	1	1	1	0.50	0.5
Public disclosure exemption requests (§ 207.81(c))	100	1	100	1	100
Total Reporting Burden					106,105

TABLE 6—ESTIMATED ANNUAL RECORDKEEPING BURDEN UNDER PART 207

SOP for creating and uploading the SPL File	Number of recordkeepers	Number of records per Recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
One-time preparation of SOP	1,000	1	1,000	40	40,000
SOP maintenance	3,295	1	3,295	1	3,295
Total					43,295

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN UNDER PART 607

21 CFR Sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Establishment Registration and Product Listing (607.22(a) and 607.25(a) and (b)(3))	68	1	68	1	68
Annual Review and Update of Establishment Registration and Blood Product Listing (607.22(a) and 607.25(a) and (b)(3))	2,615	1	2,615	0.5	1,308
Waiver requests (607.22(b))	25	1	25	1	25
Total Reporting Burden					1,401

TABLE 8—ESTIMATED ANNUAL REPORTING BURDEN UNDER PART 1271

21 CFR Sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Establishment Registration and Listing (1271.25)	225	1	225	0.75	168.75
Annual Review and Update of Establishment Registration and Listing (1271.25)	2,700	1	2,700	0.5	1,350
Waiver requests (1271.23)	100	1	100	1	100
Amend Establishment Registration (1271.26)	1,200	1	1,200	0.25	300
Total Reporting Burden					1,918.75

The information collection provisions of this final rule have been submitted to OMB for review, as required by section 3507(d) of the PRA. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following reference is on display in the Division of Dockets Management, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. It is also available electronically at *http://www.regulations.gov and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

1. FDA/Economics Staff, "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2016.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Parts 514 and 515

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 607

Blood.

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20, 201, 207, 314, 514, 515, 601, 607, and 1271 are amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

§ 20.100 [Amended]

■ 2. Amend § 20.100(c)(9) by removing "§ 207.37" and by adding in its place "§ 207.81".

■ 3. Revise § 20.116 to read as follows:

§ 20.116 Drug and device registration and listing information.

Information submitted to the Food and Drug Administration pursuant to section 510(a) through (j) of the Federal Food, Drug, and Cosmetic Act shall be subject only to the special disclosure provisions established in §§ 207.81 and 807.37 of this chapter.

PART 201—LABELING

■ 4. The authority citation for part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.1 [Amended]

■ 5. Amend § 201.1(f) by removing "§ 207.3(b)" and adding in its place "§ 207.1".

§ 201.2 [Amended]

■ 6. Amend § 201.2 by removing the last sentence.

■ 7. In § 201.25 revise the first sentence of paragraph (c)(1) introductory text to read as follows:

§ 201.25 Bar code label requirements.

* * * * *

(c) * * *

(1) Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN/UCC) or Health Industry Business Communications Council (HIBCC) standards or another standard or format that has been approved by the relevant Food and Drug Administration Center Director. * * *

* * * * *

■ 8. Revise part 207 to read as follows:

PART 207—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS, AND THE NATIONAL DRUG CODE

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207.69 What are the requirements for an official contact and a United States agent?
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Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

Subpart A—General

§ 207.1 What definitions and interpretations of terms apply to this part?

The definitions and interpretations of terms in sections 201 and 510 of the Federal Food, Drug, and Cosmetic Act apply to the terms used in this part, if not otherwise defined in this section. The following definitions apply to this part:

Active pharmaceutical ingredient means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.

Bulk drug substance, as referenced in sections 503A(b)(1)(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, means the same as "active pharmaceutical ingredient" as defined in § 207.1(b).

Commercial distribution means any distribution of a human drug, except for investigational use under part 312 of this chapter, and any distribution of an animal drug or an animal feed bearing or containing an animal drug, except for investigational use under part 511 of this chapter. The term does not include internal or interplant transfer between registered establishments under common ownership and control, including a parent, subsidiary, or affiliate company. For foreign establishments that manufacture, repack, relabel, or salvage, or for foreign private label distributors, the term "commercial distribution" has the same meaning except the term does not include distribution of any drug that is neither imported nor offered for import into the United States.

Content of labeling means:

(1) For human prescription drugs that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act: The content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(2) For human prescription drugs that are not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act: The labeling equivalent to the content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(3) For human over-the-counter (OTC) drugs: All text, tables, and figures including the drug facts labeling required by § 201.66 of this chapter.

(4) For animal drugs (including, but not limited to, drugs that are subject to section 512 of the Federal Food, Drug, and Cosmetic Act): The content of the labeling that accompanies the drug that is necessary to enable safe and proper administration of the drug (*e.g.,* the labeling applicable to veterinary drugs specified in part 201 of this chapter), including all text, tables, and figures.

Domestic for purposes of registration and listing under this part, when used to modify the term "registrant," "manufacturer," "repacker," "relabeler," "salvager," "private label distributor," or "establishment," refers to a registrant, manufacturer, repacker, relabeler, salvager, private label distributor, or establishment within any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Drug, for the purposes of registration and listing under this part, has the meaning given in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

Establishment means a place of business under one management at one general physical location. The term includes, among others, independent laboratories that engage in control activities for a registered drug establishment (*e.g.,* consulting laboratories), manufacturers of medicated feeds and of vitamin products that are drugs in accordance with section 201(g) of the Federal Food, Drug, and Cosmetic Act, human blood donor centers, and animal facilities used for the production or control testing of licensed biologicals, and establishments engaged in salvaging.

Establishment registration number means the number assigned to the establishment, as identified by FDA, after the establishment registration required in this part.

Finished drug product means a finished dosage form (*e.g.,* tablet, capsule, or solution) that contains at least one active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers.

Foreign for the purposes of registration and listing under this part:

(1) When used to modify the term "manufacturer," "repacker," "relabeler," or "salvager," refers to a manufacturer, repacker, relabeler, or salvager, who is located in a foreign country and who manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States.

(2) When used to modify the term "establishment" refers to an establishment that is located in a foreign country and is engaged in the manufacture, repackaging, relabeling, or salvaging of any drug, or any animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States.

Importer means, for purposes of this part, a person in the United States that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's drug, or an animal feed bearing or containing a new animal drug, that is imported into the United States.

Manufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug or an animal feed bearing or containing a new animal drug. Manufacture includes the making by chemical, physical, biological, or other procedures or manipulations of a drug, or an animal feed bearing or containing a new animal drug, including control procedures applied to the final product or to any part of the process. Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs for another registered establishment's drug. For purposes of this part, and in order to clarify the responsibilities of the entities engaged in different operations, the term manufacture is defined and used separately from the terms relabel, repackage, and salvage, although the term "manufacture, preparation, propagation, compounding, or processing," as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities.

Manufacturer means a person who owns or operates an establishment that manufactures a drug or an animal feed bearing or containing a new animal drug. This term includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug, or an animal feed bearing or containing a new animal drug, as defined in this paragraph. For purposes of this part, and in order to clarify the responsibilities of the entities engaged in different operations, the term manufacturer is defined and used separately from the terms relabeler, repacker, and salvager, although the term "manufacture, preparation, propagation, compounding, or processing," as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. Repackers, relabelers, and salvagers are subject to the provisions of this part that are applicable to repackers, relabelers, and salvagers, but are not subject to the provisions of this part that are applicable to manufacturers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.

Material change means any change in any drug listing information, as required under §§ 207.49, 207.53, 207.54, 207.55, or 207.57 except changes in format of labeling, labeling changes of an editorial nature, or inclusion of a bar code or initial inclusion of an NDC on the label.

Outsourcing facility means a compounder that has elected to register with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act and that meets all of the conditions of section 503B.

Person who imports or offers for import means, for purposes of this part, the owner or exporter of a drug who consigns and ships a drug from a foreign country to the United States. This includes persons who send a drug to the United States by international mail or other private delivery service, but it does not include carriers who merely transport the drug.

Private label distribution means commercial distribution of a drug under the label or trade name of a person who did not manufacture, repack, relabel, or salvage that drug.

Private label distributor means, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed.

Registrant means any person that owns or operates an establishment that manufactures, repacks, relabels, or salvages a drug, and is not otherwise exempt from establishment registration requirements under section 510 of the Federal Food, Drug, and Cosmetic Act or this part.

Relabel means to change the existing label or labels on a drug or drug package, or change or alter the existing labeling for a drug or drug package, without repacking the drug or drug package. This term does not include the addition or modification of information affixed solely for purposes of delivery to a customer, customer identification, and/or inventory management.

Relabeler means a person who owns or operates an establishment that relabels a drug. When not modified by "domestic" or "foreign," the term includes both domestic relabelers and foreign relabelers.

Repack or repackage means the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.

Repacker means a person who owns or operates an establishment that repacks a drug or drug package. When not modified by "domestic" or "foreign," the term includes both domestic repackers and foreign repackers.

Representative sampling of advertisements means typical advertising material (including the promotional material described in § 202.1(l)(1) of this chapter, but excluding labeling as determined in § 202.1(l)(2) of this chapter), that gives a balanced picture of the promotional claims used for the drug.

Representative sampling of any other labeling means typical labeling material (including the labeling material described in § 202.1(l)(2) of this chapter, but excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug.

Salvage means the act of segregating out those finished drug products that may have been subjected to improper storage conditions (such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation) for the purpose of returning the products to the marketplace and includes applying manufacturing controls such as those required by current good manufacturing practice in parts 210 and 211 of this chapter.

Salvager means a person who owns or operates an establishment that engages in salvaging. When not modified by "domestic" or "foreign," the term includes both domestic and foreign salvagers.

Unfinished drug means an active pharmaceutical ingredient either alone or together with one or more other ingredients but does not include finished drug products.

§ 207.3 Bulk drug substance.

Bulk drug substance, as referenced in sections 503A(b)(1)(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in § 207.3(a)(4), means the same as "active pharmaceutical ingredient" as defined in § 207.1(b).

§ 207.5 What is the purpose of this part?

Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Both types of information facilitate implementation and enforcement of the Federal Food, Drug, and Cosmetic Act and are used for many important public health purposes.

§ 207.9 Who does this part cover?

(a) Except as provided in paragraph (b) of this section, this part applies to:

(1) Domestic manufacturers, domestic repackers, domestic relabelers and domestic salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or § 207.13, regardless of whether their drugs enter interstate commerce;

(2) Foreign manufacturers, foreign repackers, foreign relabelers and foreign salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or § 207.13;

(3) Private label distributors, because they must have labeler codes;

(4) Establishments engaged in the manufacture, repacking, relabeling, or salvaging of human drugs regulated under a biologics license application (BLA). These establishments are subject to the requirements of this part unless they are required to register and list such drugs as human blood or blood products under part 607 of this chapter and do not engage in activities that would otherwise require them to register and list under this part.

(5) Establishments engaged in the manufacture (as defined in § 1271.3(e) of this chapter) of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (as defined in § 1271.3(d) of this chapter) that, under § 1271.20 of this chapter, are also drugs regulated under section 351 of the Public Health Service Act or section 505 of the Federal Food, Drug, and Cosmetic Act. These establishments must register and list those HCT/Ps following the procedures described in this part.

(b) This part does not apply to owners and operators of establishments that collect or process human whole blood and blood products unless the establishment also manufactures, repacks, or relabels other drugs. For purposes of this paragraph (b), human whole blood and blood products do not include plasma derivatives such as albumin, Immune Globulin, Factor VIII and Factor IX, and recombinant versions of plasma derivatives or animal derived plasma derivatives, or bulk product substances such as fractionation intermediates or pastes. Establishments that collect or process human whole blood and blood products as well as establishments involved in testing of human whole blood and blood products must register and list under part 607 of this chapter. Manufacturers of licensed devices and manufacturers of licensed biological products used in a licensed device must register and list under part 607 of this chapter.

(c) This part does not apply to establishments that solely manufacture, prepare, propagate, compound, assemble, or process medical devices. Registration and listing regulations for such establishments are codified in part 807 of this chapter.

§ 207.13 Who is exempt from the registration and listing requirements?

Except as provided in § 207.13(l), the following classes of persons are exempt from registration and drug listing in accordance with section 510(g) of the Federal Food, Drug, and Cosmetic Act or because FDA has determined, under section 510(g)(5) of the Federal Food, Drug, and Cosmetic Act, that their registration is not necessary for the protection of the public health. This exemption is limited to establishment registration and drug listing requirements and does not relieve a person from other statutory or regulatory obligations.

(a)(1) Pharmacies that:

(i) Operate in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs upon a valid prescription by practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture, repack, relabel, or salvage drugs other than in the regular course of their business of dispensing or selling drugs at retail.

(2) The exemption in this paragraph (a) is limited to pharmacies located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Hospitals, clinics, other health care entities, and public health agencies that:

(i) Operate establishments in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs, other than human whole blood or blood products, upon a valid order or prescription by practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture, repack, relabel, or salvage drugs other than in the regular course of their practice of pharmacy, including dispensing.

(2) The exemption in this paragraph (b) is limited to hospitals, clinics, other health care entities, and public health agencies located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(c) Individuals or establishments under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment to become components of a biological product are exempt from registration and listing under this part unless FDA determines that drug establishment registration and listing is necessary for the protection of the public health.

(d) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture, repack, relabel, or salvage drugs solely for use in their professional practice.

(e) Manufacturers, repackers, relabelers, or salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale.

(f) Manufacturers, repackers, and relabelers of harmless inactive ingredients such as excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs.

(g) Manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds, except for persons who manufacture, repack, relabel, or salvage Type B or Type C medicated feeds starting from Category II, Type A medicated articles for which a medicated feed mill license approved under part 515 of this chapter is required. This exemption also does not apply to persons that would otherwise be required to register (such as manufacturers, repackers, relabelers, or salvagers of certain free-choice feeds, as defined in § 510.455 of this chapter, or certain liquid feeds, as defined in § 558.5 of this chapter, where the specifications and/or formulas are not published and a medicated feed mill license is required). All manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds are exempt from listing.

(h) Any manufacturer, repacker, relabeler, or salvager of a virus, serum, toxin, or analogous product intended for the treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)), provided that this exemption from registration applies only to the manufacturer, repacker, relabeler, or salvager of that animal virus, serum, toxin, or analogous product.

(i) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

(j) Foreign establishments whose drugs are imported or offered for import into the United States must comply with the establishment registration and listing requirements of this part unless exempt under this section or unless:

(1) Their drugs enter a foreign trade zone and are re-exported without having entered U.S. commerce, or

(2) Their drugs are imported in conformance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act.

(k) Entities that are registered with FDA as outsourcing facilities and that compound drugs in conformance with section 503B of the Federal Food, Drug, and Cosmetic Act.

(l) The exemptions provided in paragraphs (a) through (k) of this section do not apply to such persons if they:

(1) Manufacture (as defined in § 207.1(b)), repack, relabel, or salvage compounded positron emission tomography drugs as defined in section 201(ii) of the Federal Food, Drug, and Cosmetic Act;

(2) Manufacture (as defined in § 600.3(u) of this chapter) a human biological product subject to licensing under section 351 of the Public Health Service Act; or

(3) Engage in activities that would otherwise require them to register under this part.

Subpart B—Registration

§ 207.17 Who must register?

(a) Unless exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or this part, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments.

(b) Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under this part. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

§ 207.21 When must initial registration information be provided?

(a) Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment.

(b) Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.

§ 207.25 What information is required for registration?

Registrants must provide the following information:

(a) Name of the owner or operator of each establishment; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(b) Each establishment's name, physical address, and telephone number(s);

(c) All name(s) of the establishment, including names under which the establishment conducts business or names by which the establishment is known;

(d) Registration number of each establishment, if previously assigned by FDA;

(e) A Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.

(f) All types of operations performed at each establishment;

(g) Name, mailing address, telephone number, and email address of the official contact for the establishment, as provided in § 207.69(a); and

(h) Additionally, with respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for:

(1) The United States agent, as provided in § 207.69(b);

(2) Each importer in the United States of drugs manufactured, repacked, relabeled, or salvaged at the establishment that is known to the establishment; and

(3) Each person who imports or offers for import such drug to the United States.

§ 207.29 What are the requirements for reviewing and updating registration information?

(a) *Expedited updates.* Registrants must update their registration information no later than 30 calendar days after:

(1) Closing or selling an establishment;

(2) Changing an establishment's name or physical address; or

(3) Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent. A registrant, official contact, or United States agent may notify FDA about a change of information for the designated official contact or United States agent, but only a registrant is permitted to designate a new official contact or United States agent.

(b) *Annual review and update of registration information.* Registrants must review and update all registration information required under § 207.25 for each establishment.

(1) The first review and update must occur during the period beginning on October 1 and ending December 31 of the year of initial registration, if the initial registration occurs prior to October 1. Subsequent reviews and updates must occur annually, during the period beginning on October 1 and ending December 31 of each calendar year.

(2) The updates must reflect all changes that have occurred since the last annual review and update.

(3) If no changes have occurred since the last registration, registrants must certify that no changes have occurred.

Subpart C—National Drug Code

§ 207.33 What is the National Drug Code (NDC), how is it assigned, and what are its requirements?

(a) *What is the NDC for a drug and what products must have unique NDCs?* The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type.

(b) *What is the format of an NDC?* (1) Except as described in paragraph (b)(4) of this section, the NDC must consist of 10 or 11 digits, divided into three segments as follows:

(i) The first segment of the NDC is the labeler code and consists of 4, 5, or 6 digits. The labeler code is assigned by FDA.

(ii) The second segment of the NDC is the product code and consists of 3 or 4 digits, as specified in paragraphs (b)(2) and (3) of this section.

(iii) The third segment of the NDC is the package code and consists of 1 or 2 digits as specified in paragraphs (b)(2) and (3) of this section. The package code identifies the package size and type of the drug and differentiates between different quantitative and qualitative attributes of the product packaging.

(2) The following combinations of labeler code, product code and package code character lengths are permissible:

(i) If a labeler code is either 5 or 6 digits in length, it may be combined with:

(A) A product code consisting of 4 digits and a package code consisting of 1 digit for a total NDC length of 10 or 11 digits (5–4–1 or 6–4–1), or

(B) A product code consisting of 3 digits and a package code consisting of 2 digits for a total NDC length of 10 or 11 digits (5–3–2 or 6–3–2).

(ii) If a labeler code is 4 digits in length, it may be combined only with a product code consisting of 4 digits and a package code consisting of 2 digits for a total NDC length of 10 digits (4–4–2).

(3) A registrant or private label distributor with a given labeler code must use only one Product-Package Code configuration (*e.g.,* a 3-digit product code combined with a 2-digit package code or a 4-digit product code combined with a 1-digit package code). This single configuration must be used in all NDCs that include the given labeler code that are reserved in accordance with § 207.33(d)(3) or listed in accordance with § 207.49 or § 207.53.

(4) An alternatively formatted NDC that is approved for use by the relevant Center Director may be used for the following HCT/Ps if they are minimally

manipulated: Hematopoietic stem/progenitor cells derived from peripheral and cord blood, and lymphocytes collected from peripheral blood.

(c) *Who must obtain an NDC labeler code and how is the code assigned and updated*? (1) Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under this part must apply for an NDC labeler code, by providing the following information:

(i) The name, physical address, email address, and other contact information FDA may request, of the person for whom the NDC labeler code is requested;

(ii) The type(s) of activities (*e.g.*, manufacture or repacking) in which the person requesting the NDC labeler code engages with respect to human drugs; and

(iii) The type(s) of drug(s) (human, animal, or both, and prescription, nonprescription, or both) to which the NDC labeler code will be applied.

(2) Each person who is assigned an NDC labeler code must update the information submitted under paragraph (c)(1)of this section within 30 calendar days after any change to that information.

(d) *How is an NDC proposed for assignment by FDA, when is an NDC assigned by FDA, and how can a proposed NDC be reserved*? (1) An NDC is proposed for assignment by FDA when it is submitted for the first time with listing information in accordance with § 207.49 or § 207.53, as applicable.

(i) Each manufacturer, repacker, or relabeler must propose for assignment by FDA an NDC that includes its own labeler code for each package size and type of drug that it manufactures, repacks, or relabels for commercial distribution.

(ii) In addition, if a drug is distributed under the trade name or label of a private label distributor, the manufacturer, repacker, or relabeler must also propose for assignment by FDA an NDC that includes the labeler code of the private label distributor under whose trade name or label the drug is distributed, for each package size and type so distributed.

(2) If a proposed NDC conforms to the requirements of this section and is not reserved for a different drug or was not previously assigned to a different drug, FDA will assign the NDC to a drug when it receives listing information required for that drug under § 207.49 or § 207.53.

(3) A manufacturer, repacker, relabeler, or private label distributor may voluntarily reserve a proposed NDC for a drug, before the drug is listed, by submitting the following information:

(i) A proposed NDC that conforms to the requirements of this section;

(ii) The established name of the active ingredient(s) and the strength of each active ingredient in the drug; and

(iii) In the case of a finished drug product, the dosage form, and route of administration.

(4) If the required information is submitted and the proposed NDC is properly formatted and not already assigned or reserved, FDA will reserve the proposed NDC for a period of 2 years from the date of submission. If the drug for which the proposed NDC is reserved is not listed in accordance with § 207.49 or § 207.53 during such 2-year period, the reservation of the proposed NDC will lapse. FDA may also cancel the reservation of a proposed NDC at any time on the request of the person whose labeler code is included in the proposed NDC.

(e) *How must the information be submitted to us*? The information described in paragraphs (c) and (d) of this section must be submitted electronically unless FDA grants a waiver under § 207.65.

§ 207.35 What changes require a new NDC?

(a) Once an NDC has been assigned by FDA, the registrant must propose a new and unique NDC for a drug when there is a change, after the drug is initially marketed, to any of the information identified in paragraphs (b) and (c) of this section. A new NDC must be proposed to FDA for assignment through an updated listing in accordance with § 207.57.

(b) The proposed new NDC must include a new product code when there is a change to any of the following information:

(1) The drug's established name or proprietary name, if any;

(2) Any active pharmaceutical ingredient or the strength of any active pharmaceutical ingredient;

(3) The dosage form;

(4) A change in the drug's status, between prescription and nonprescription, or for animal drugs, between prescription, nonprescription, or veterinary feed directive (VFD) status;

(5) A change in the drug's intended use between human and animal; or

(6) The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any).

(c) When there is a change only to the package size or type, including the immediate unit-of-use container, if any, the proposed new NDC must include only a new package code and retain the existing product code unless all available package codes have already been combined with the existing product code in NDCs assigned by FDA.

§ 207.37 What restrictions pertain to the use of the NDC?

(a) A product may be deemed to be misbranded if an NDC is used:

(1) To represent a different drug than the drug for which the NDC has been assigned, as described in § 207.33;

(2) To denote or imply FDA approval of a drug; or

(3) On products that are not subject to parts 207, 607 of this chapter, or 1271 of this chapter, such as dietary supplements and medical devices.

(b) If marketing is resumed for a discontinued drug, and no changes have been made to the drug that would require a new NDC under § 207.35, the drug must have the same NDC that was assigned to it as described in § 207.33, before marketing was discontinued.

Subpart D—Listing

§ 207.41 Who must list drugs and what drugs must they list?

(a) Each registrant must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution. Each domestic registrant must list each such drug regardless of whether the drug enters interstate commerce. When operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. A drug manufactured, repacked, or relabeled for private label distribution must be listed in accordance with paragraph (c) of this section.

(b) Registrants must provide listing information for each drug in accordance with the listing requirements described in §§ 207.49, 207.53, and 207.54 that correspond to the activity or activities they engage in for that drug.

(c)(1) For both animal and human drugs, each registrant must list each drug it manufactures, repacks, or relabels for commercial distribution under the trade name or label of a private label distributor using an NDC that includes such private label distributor's labeler code.

(2) Additionally, in the case of human drugs, each registrant must list each human drug it manufactures, repacks, or relabels using an NDC that includes the registrant's own labeler code, regardless of whether the drug is commercially distributed under the registrant's own label or trade name or under the label

or trade name of a private label distributor.

§ 207.45 When, after initial registration of an establishment, must drug listing information be submitted?

For each drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at an establishment at the time of initial registration, drug listing information must be submitted no later than 3 calendar days after the initial registration of the establishment.

§ 207.49 What listing information must a registrant submit for a drug it manufactures?

(a) Each registrant must provide the following listing information for each drug it manufactures for commercial distribution.

(1) The appropriate NDC(s), as described in § 207.33, that include all package code variations. In the case of human drugs, the appropriate NDC(s) submitted under this paragraph include the registrant's labeler code. In the case of animal drugs, the appropriate NDC(s) submitted under this paragraph include the registrant's labeler code, except that when the drug is manufactured for commercial distribution under the trade name or label of a private label distributor, the appropriate NDC(s) for animal drugs include the private label distributor's labeler code;

(2) Package type and volume information corresponding to the package code segment of the NDC;

(3) The listed drug's established name and proprietary name, if any;

(4) The name and quantity of each active pharmaceutical ingredient in the listed drug;

(5) The name of each inactive ingredient in the listed drug, along with any assertions of confidentiality associated with individual inactive ingredients;

(6) The dosage form;

(7) The drug's approved U.S. application number, if any;

(8) The drug type (*e.g.*, as applicable, finished vs. unfinished, human vs. animal, prescription vs. nonprescription);

(9) In the case of an unfinished drug, the number assigned to the Drug Master File or Veterinary Master File, if any, that describes the manufacture of the drug;

(10) For each drug that is subject to the imprinting requirements of part 206 of this chapter including products that are exempted under § 206.7(b), the drug's size, shape, color, scoring, and code imprint (if any);

(11) The route or routes of administration of the drug;

(12) For each drug bearing an NDC:

(i) The name and Unique Facility Identifier of the establishment where the registrant who lists the drug manufactures it and the type of operation performed on the drug at that establishment, and

(ii) The name and Unique Facility Identifier of every other establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment. This includes all establishments involved in the production of each unfinished drug received by the registrant for use in the production of the drug being listed. The names, Unique Facility Identifiers, and type of operations for establishments involved in production of each unfinished drug received by the registrant for use in the production of the drug being listed may be provided by including the properly assigned and listed NDC for such unfinished drug.

(13) The schedule of the drug under section 202 of the Controlled Substances Act, if applicable;

(14) Advertisements:

(i) A representative sampling of advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(ii) If FDA requests it, for good cause, a copy of all advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, including those advertisements described in § 202.1(*l*)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after FDA's request.

(15) For drugs bearing the NDC(s) reported under paragraph (a)(1) of this section, except those drugs manufactured exclusively for private label distribution and not distributed under the registrant's own name and label, provide the following labeling, as applicable:

(i) *Human prescription drugs.* All current labeling except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1(b).

(ii) *Human nonprescription drugs.* (A) For each human nonprescription drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1(b).

(B) For each human nonprescription drug not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), the package insert (if any), and a representative sampling of any other labeling. This labeling submission must include the content of labeling as defined in section § 207.1(b).

(iii) *Animal drugs.* (A) For each animal drug that is subject to section 512 of the Federal Food, Drug, and Cosmetic Act, which includes, but is not limited to, new animal drugs that have been approved, conditionally approved, or indexed under sections 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), including the content of labeling as defined in § 207.1(b);

(B) For all other animal drugs, a copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, the content of labeling as defined in § 207.1(b), and a representative sampling of any other labeling;

(iv) *All other listed drugs.* For all other listed drugs, including unfinished drugs, the label (if any), except that only one representative label need be submitted where differences exist only in the quantity of contents statement.

(16) Listing submissions described in § 207.41(c)(2) for human drugs manufactured for private label distribution must include all information specified in § 207.49(a)(2) through (14) and:

(i) The appropriate NDC(s) (as described in § 207.33) that include the private label distributor's labeler code and all package code variations;

(ii) The name, mailing address, telephone number, and email address of the private label distributor; and

(iii) For drugs bearing the NDC(s) reported under paragraph (a)(16)(i) of this section, labeling as described in paragraph (a)(15) of this section that accompanies the private label distributor's product.

(b) Additionally, each registrant is requested, but not required, to provide the following information for each human drug it manufactures for commercial distribution:

(1) The drug's over-the-counter monograph reference, if any; and

(2) The date on which the drug was or will be introduced into commercial distribution.

§ 207.53 What listing information must a registrant submit for a drug that it repacks or relabels?

Each registrant must provide the following listing information for each drug it repacks or relabels:

(a) *NDC.* The appropriate NDC(s), as described in § 207.33, that include the registrant's labeler code and all package code variations;

(b) *Source NDC.* The NDC assigned to each finished drug received by the registrant for repacking or relabeling, with the exception of medical gases. Each such NDC must be associated with the corresponding NDC(s) for repacked or relabeled drugs, reported under paragraph (a) of this section.

(c) *Name and Unique Facility Identifier.* For each drug identified by an NDC reported under paragraph (a) of this section, the name and Unique Facility Identifier of every establishment where repacking or relabeling is performed for the drug and the type of operation (repacking vs. relabeling) performed at each such establishment.

(d) *Labeling.* For each drug identified by an NDC reported under paragraph (a) of this section, except those human drugs repacked or relabeled exclusively for private label distribution and not distributed under the registrant's own name and label, provide the following:

(1) *Human prescription drugs.* All current labeling for the repacked or relabeled drug except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in section § 207.1(b).

(2) *Human nonprescription drugs.* (i) For each human nonprescription drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1(b).

(ii) For each human nonprescription drug not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), the package insert (if any), and a representative sampling of any other labeling. This labeling submission must include the content of labeling as defined in § 207.1(b).

(3) *Animal drugs.* (i) For each animal drug that is subject to section 512 of the Federal Food, Drug, and Cosmetic Act, which includes but is not limited to, new animal drugs that have been approved, conditionally approved, or indexed under sections 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), including the content of labeling as defined in § 207.1(b);

(ii) For all other animal drugs, a copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, the content of labeling as defined in § 207.1(b), and a representative sampling of any other labeling;

(4) *All other.* For all other listed drugs, including unfinished drugs, the label (if any), except that only one representative label need be submitted where differences exist only in the quantity of contents statement.

(e) *Advertisements.* (1) A representative sampling of advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(2) If we request it for good cause, a copy of all advertisements for a particular drug described in paragraph (e)(1) of this section, including advertisements described in § 202.1(l)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after our request.

(f) *Private label distributor products.* A listing submission for a human drug distributed by a private label distributor described in § 207.41(c)(2) must include information specified in § 207.53(b) through (e) as applicable and:

(1) The appropriate NDC(s) (as described in § 207.33) that include the private label distributor's labeler code and all package code variations;

(2) The name, mailing address, telephone number, and email address of the private label distributor; and

(3) For drugs bearing the NDC(s) reported under paragraph (f)(1) of this section, labeling as described in paragraphs (d)(1) through (4) of this section, as applicable, that accompanies the private label distributor's product.

§ 207.54 What listing information must a registrant submit for a drug that it salvages?

A registrant who also relabels or repacks a drug that it salvages must list the drug it relabels or repacks in accordance with § 207.53 rather than in accordance with this section. A registrant who performs only salvaging with respect to a drug must provide the following listing information for that drug.

(a) The NDC assigned to the drug immediately before the drug is received by the registrant for salvaging;

(b) The lot number and expiration date of the salvaged drug product; and

(c) The name and Unique Facility Identifier for each establishment where the registrant salvages the drug.

§ 207.55 What additional drug listing information may FDA require?

For a particular listed drug, upon our request, the registrant must briefly state the basis for its belief that the drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

§ 207.57 What information must registrants submit when updating listing information and when?

Registrants must review and update listing information at a minimum, as follows:

(a) Registrants must provide listing information at the time of annual establishment registration for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been listed previously.

(b) Registrants must review and update their drug listing information each June and December. When doing so, registrants must:

(1)(i) Provide listing information, in accordance with §§ 207.49, 207.53, and 207.54, for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been previously listed;

(ii) Submit the date that they discontinued the manufacture, repacking, relabeling or salvaging for commercial distribution of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled, or salvaged;

(iii) Submit the date that they resumed the manufacture, repacking, or relabeling for commercial distribution of a drug previously discontinued, and provide any required listing information not previously submitted; and

(iv) Submit any material changes in any information previously submitted pursuant to §§ 207.49, 207.53, 207.54, or other relevant sections of this part; or

(2) For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single "no changes" certification during the annual registration update under § 207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.

(c) Registrants are encouraged to submit listing information for every drug subject to listing under this part prior to commercial distribution and are encouraged to update listing information at the time of any change affecting information previously submitted.

Subpart E—Electronic Format for Registration and Listing

§ 207.61 How is registration and listing information provided to FDA?

(a) *Electronic format.* (1) Except as provided in § 207.65, all information submitted under this part must be transmitted to FDA in electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. We may periodically issue guidance on how to provide registration and listing information in electronic format (specifying for example method of transmission, media, file formats, preparation, and organization of files).

(2) Information provided in electronic format must comply with part 11 of this chapter, except as follows:

(i) Advertisements and labeling, including the content of labeling, required under this part are exempt from the requirements in § 11.10(a), (c) through (h), and (k) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(ii) All other information submitted under this part is exempt from the requirements in § 11.10(b), (c), and (e) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(b) *English language.* Drug establishment registration and drug listing information must be provided in the English language. The content of labeling must be provided at a minimum in the English language. Where § 201.15(c) of this chapter permits product labeling solely in a foreign language, the content of labeling must be submitted in that language along with an accurate English translation.

§ 207.65 How can a waiver of the electronic submission requirement be obtained?

(a) All information submitted under this part must be transmitted to FDA electronically in accordance with § 207.61(a) unless FDA has granted a request for waiver of this requirement prior to the date on which submission of such information is due. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. All waiver requests must be sent to: SPL Coordinator, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993.

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable.

Subpart F—Miscellaneous

§ 207.69 What are the requirements for an official contact and a United States agent?

(a) *Official contact.* Registrants subject to the registration requirements of this part must designate an official contact for each establishment. The official contact is responsible for:

(1) Ensuring the accuracy of registration and listing information; and

(2) Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications.

(b) *United States agent.* Registrants of foreign establishments subject to this part must designate a single United States agent. The United States agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present. The United States agent is responsible for:

(1) Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications;

(2) Responding to questions concerning those drugs that are imported or offered for import to the United States;

(3) Assisting FDA in scheduling inspections; and

(4) If FDA is unable to contact a foreign registrant directly or expeditiously, FDA may provide the information and/or documents to the United States agent. FDA's providing information and/or documents to the United States agent is equivalent to providing the same information and/or documents to the foreign registrant.

§ 207.77 What legal status is conferred by registration and listing?

(a) Registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing is misleading and constitutes misbranding.

(b) FDA's acceptance of registration and listing information, inclusion of a drug in our database of drugs, or assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed. Any representation that creates the impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned or displays an NDC, or the establishment has been assigned an establishment registration number or Unique Facility Identifier is misleading and constitutes misbranding. Failure to comply with § 207.37 may also constitute misbranding.

(c) Neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Registration or listing may, however, be evidence that a facility intends to or does manufacture, repack, relabel, distribute, or salvage drugs or that a product is intended to be a drug.

§ 207.81 What registration and listing information will FDA make available for public disclosure?

(a) Except as provided in paragraphs (b) and (c) of this section, the following information will be available for public disclosure, upon request or at FDA's discretion:

(1) All establishment registration information, and

(2) After a drug is marketed, information obtained under § 207.33, § 207.49, § 207.53, § 207.54, or § 207.57.

(b) Unless such information is publicly available or FDA finds that confidentiality would be inconsistent with protection of the public health, FDA will not make publicly available:

(1) Any information submitted under § 207.55 as the basis upon which it has been determined that a particular drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act,

(2) The names of any inactive ingredients submitted under § 207.49(a)(4) for which the registrant makes a valid assertion of confidentiality under § 20.61 of this chapter or other provision of law, or

(3) Drug listing information obtained under § 207.33(d)(3), § 207.49(a)(9) and (12), § 207.53(b) and (c), or § 207.54(a) or (c).

(c) FDA may determine, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health and the Freedom of Information Act to exempt from public disclosure specific information identified in paragraph (a) of this section.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 9. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 356e, 371, 374, 379e, 379k–1.

■ 10. In § 314.81, revise paragraph (b)(3)(iv) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iv) *Withdrawal of approved drug product from sale.* (*a*) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are manufacturers, repackers, or relabelers subject to part 207 of this chapter must submit the following information about the drug, in accordance with the applicable requirements described in §§ 207.61 and 207.65:

(*1*) The National Drug Code (NDC);

(*2*) The identity of the drug by established name and by proprietary name, if any;

(*3*) The new drug application number or abbreviated application number;

(*4*) The date on which the drug is expected to be no longer in commercial distribution. FDA requests that the reason for withdrawal of the drug from sale be included with the information.

(*b*) Within 30 calendar days of the withdrawal of an approved drug from sale, applicants who are not subject to part 207 of this chapter must submit the information listed in paragraphs (b)(3)(iv)(*a*)(*1*) through (*4*) of this section. The information must be submitted either electronically or in writing to the Drug Registration and Listing Office, Food and Drug Administration, Center for Drug Evaluation and Research.

(*c*) Reporting under paragraph (b)(3)(iv)(*a*) of this section constitutes compliance with the requirements of § 207.57 of this chapter to update drug listing information with respect to the withdrawal from sale.

* * * * *

§ 314.125 [Amended]

■ 11. Amend § 314.125 in paragraph (b)(11) by removing the words "or processed".

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 12. The authority citation for part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

■ 13. In § 514.111 add paragraph (a)(12) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(12) The drug will be produced in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the Federal Food, Drug, and Cosmetic Act and part 207 of this chapter.

* * * * *

PART 515—MEDICATED FEED MILL LICENSE

■ 14. The authority citation for part 515 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 515.10 [Amended]

■ 15. In § 515.10(b)(8), remove the phrase "§§ 207.20 and 207.21" and add in its place the phrase "part 207".

PART 601—LICENSING

■ 16. The authority citation for part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 17. In § 601.2, add paragraph (f) to read as follows:

§ 601.2 Applications for biologics licenses; procedures for filing.

* * * * *

(f) *Withdrawal from sale of approved biological products.* A holder of a biologics license application (BLA) must report to FDA, in accordance with the requirements of §§ 207.61 and 207.65, the withdrawal from sale of an approved biological product. The information must be submitted to FDA within 30 working days of the biological product's withdrawal from sale. The following information must be submitted: The holder's name; product name; BLA number; the National Drug Code; and the date on which the product is expected to be no longer in commercial distribution. The reason for the withdrawal of the biological product is requested but not required to be submitted.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS AND LICENSED DEVICES

■ 18. The authority citation for part 607 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

■ 19. Revise the heading for part 607 to read as set forth above.

■ 20. Add § 607.1 to subpart A to read as follows:

§ 607.1 Scope.

(a) This part establishes establishment registration and product listing requirements for manufacturers of human blood and blood products.

(b) This part establishes establishment registration and product listing requirements for manufacturers of products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health

Service Act, as well as licensed biological products used in the manufacture of a licensed device.

■ 21. In § 607.3 revise the second sentence in paragraph (b) and add paragraphs (k) and (*l*) to read as follows:

§ 607.3 Definitions.

* * * * *

(b) * * * For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act, as well as licensed biological products used in the manufacture of a licensed device.

* * * * *

(k) *Importer* means a person in the United States that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's blood product that is imported into the United States.

(*l*) *Foreign* for the purpose of registration and listing under this part when used to modify the term "establishment" refers to an establishment that is located in a foreign country and is the site where a blood product that is imported or offered for import into the United States was manufactured.

■ 22. Revise § 607.7 to read as follows:

§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

All owners or operators of establishments that engage in the manufacturing of blood products are required to register, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act. Registration and listing of blood products must comply with this part. Registration does not permit any blood bank or similar establishment to ship blood products in interstate commerce.

■ 23. In § 607.20 revise the first sentence in paragraph (c) to read as follows:

§ 607.20 Who must register and submit a blood product list.

* * * * *

(c) Except in the case of licensed device manufacturers, no registration fee is required. * * *

■ 24. In § 607.21 revise the last sentence to read as follows:

§ 607.21 Times for establishment registration and blood product listing.

* * * Owners or operators of all establishments so engaged must register annually between October 1 and December 31 and must update their blood product listing every June and December.

■ 25. Revise § 607.22 to read as follows:

§ 607.22 How to register establishments and list blood products.

(a) Initial and subsequent registrations and product listings must be submitted electronically through the Blood Establishment Registration and Product Listing system, or any future superseding electronic system. This information must be submitted in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30. All information submitted under this part must be transmitted to FDA electronically unless FDA has granted a request for waiver of this requirement prior to the date on which the information is due. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. All waiver requests must be sent to the Director of FDA's Center for Biologics Evaluation and Research through the Document Control Center (see addresses *in* § 600.2).

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable.

■ 26. Revise § 607.25 to read as follows:

§ 607.25 Information required for establishment registration and blood product listing.

(a) The Blood Establishment Registration and Product Listing system requires furnishing or confirming registration information required by the Federal Food, Drug, and Cosmetic Act. This information includes the name and street address of the establishment, including post office code; a registration number if previously assigned by FDA and a Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned partnership, or corporation); and the name of the owner or operator of such establishment. The term "name of the owner or operator" must include, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporate officer and director and the name of the State of incorporation. The information required must be given separately for each establishment, as defined in § 607.3(c).

(b) The following information must also be provided:

(1) A list of blood products by established name as defined in section 502(e) of the Federal Food, Drug, and Cosmetic Act and by proprietary name, if any, which are being manufactured for commercial distribution at the identified establishment and which have not been included in any list previously submitted to FDA through the Blood Establishment Registration and Product Listing system or any future superseding electronic system.

(2) For each blood product so listed that is subject to section 351 of the Public Health Service Act, the license number of the manufacturer issued by the Center for Biologics Evaluation and Research, Food and Drug Administration.

(3) For each blood product listed, the registration number if previously assigned by FDA and the Unique Facility Identifier of the parent establishment. An establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.

■ 27. In § 607.26 revise the first sentence to read as follows:

§ 607.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, location, or blood product handling activity must be submitted electronically through the Blood Establishment Registration and Product Listing system, or any future superseding electronic system, as an amendment to registration within 5 calendar days of such changes. * * *

■ 28. In § 607.30 revise the introductory text of paragraph (a) to read as follows:

§ 607.30 Updating blood product listing information.

(a) After submission of the initial blood product listing information, every person who is required to list blood products under § 607.20 must submit electronically through the Blood Establishment Registration and Product

Listing system, or any future superseding electronic system, at a minimum once in June and December of every year, the following information:

* * * * *

■ 29. Revise § 607.35 to read as follows:

§ 607.35 Blood product establishment registration number.

An establishment registration number will be assigned to each blood product establishment registered in accordance with this part.

■ 30. Revise § 607.37 to read as follows:

§ 607.37 Public disclosure of establishment registration and blood product listing information.

(a) Except as provided in paragraph (b) of this section, all registration and listing information obtained under §§ 607.25, 607.26, and 607.30 will be made available for public disclosure through the Center for Biologics Evaluation and Research (CBER) Blood Establishment Registration Database Web site by using the CBER electronic Web-based application or by going in person to the Food and Drug Administration, Division of Freedom of Information Public Reading Room (see addresses in § 20.120(a) of this chapter).

(b) FDA may find, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health to exempt from public disclosure specific listing information obtained under § 607.25 or § 607.30.

(c) Other requests for information regarding blood establishment registrations and blood product listings should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research Office of Communication, Outreach, and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002.

■ 31. Revise § 607.39 to read as follows:

§ 607.39 Misbranding by reference to establishment registration, validation of registration, or to registration number.

Registration of an establishment, validation of registration, or assignment of a registration number does not in any way denote approval of the firm or its products nor does it mean that the products may be legally marketed. Any representation that creates an impression of official approval because of establishment registration, validation of registration, or possession of a registration number is misleading and constitutes misbranding.

■ 32. In § 607.40 revise paragraphs (d) introductory text and (d)(3) and add paragraph (e) to read as follows:

§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

* * * * *

(d) Each foreign establishment required to register under paragraph (a) of this section must submit the name, address, telephone number, and email address of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment must designate only one United States agent.

* * * * *

(3) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone number, or email address to FDA within 30 calendar days of the change.

(e) Each foreign establishment required to register under paragraph (a) of this section must register and list blood products using the Blood Establishment Registration and Product Listing system, or any superseding electronic system, unless FDA waives the electronic submission requirement in accordance with § 607.22.

■ 33. In § 607.65 add paragraph (g) to read as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(g) Persons who engage solely in the production of any plasma derivative, including, but not limited to, albumin, Immune Globulin, Factor VIII and Factor IX, bulk product substances such as fractionation intermediates or pastes, or recombinant versions of plasma derivatives or animal derived plasma derivatives. These persons must register and list under part 207 of this chapter.

■ 34. Add subpart E, consisting of § 607.80, to part 607 to read as follows:

Subpart E—Establishment Registration and Product Listing Of Licensed Devices

§ 607.80 Applicability of part 607 to licensed devices.

Manufacturers of products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act, as well as licensed biological products used in the manufacture of a licensed device, must register and list following the procedures under this part, with respect to their manufacture of those products, unless otherwise noted in this section.

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 35. The authority citation for part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

§ 1271.1 [Amended]

■ 36. Amend § 1271.1 in paragraphs (a) and (b)(2) by removing "207.20(f)" and adding in its place "207.9(a)(5)"; in paragraph (a) by removing the term "a unified" and adding in its place the term "an electronic"; and in paragraph (b)(2) by removing the phrase "in subpart B of this part" and adding in its place the phrase "in part 207 (if a drug and/or biological product) of this chapter or part 807 (if a device) of this chapter".

■ 37. In § 1271.3 add paragraphs (mm) and (nn) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(mm) *Importer* means a company or individual in the United States that is the owner, consignee, or recipient, at the time of entry, of the foreign establishment's HCT/P that is imported into the United States.

(nn) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

§ 1271.20 [Amended]

■ 38. Amend § 1271.20 by removing "207.20(f)" and adding in its place "207.9(a)(5)" and by removing the phrase "subparts B, C, and D of this part" and adding in its place "subparts C and D of this part".

■ 39. Revise § 1271.22 to read as follows:

§ 1271.22 How do I register and submit an HCT/P list?

(a) You must use the electronic registration and listing system at *http://www.fda.gov/cber/tissue/tisreg.htm* in accordance with § 1271.25 for:

(1) Establishment registration,

(2) HCT/P listings, and

(3) Updates of registration and HCT/P listing.

(b) FDA will periodically issue guidance on recommended procedures for providing registration and listing information in electronic format (for example, method of transmission, media, file formats, preparation, and organization of files).

(c) You must provide the information under paragraph (a) of this section in accordance with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e) and the corresponding requirements in § 11.30.

■ 40. Add § 1271.23 to subpart B to read as follows:

§ 1271.23 How is a waiver from the electronic format requirements requested?

(a) You may request a waiver from the requirement in § 1271.22 that information must be provided to FDA in electronic format. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. Waiver requests may be sent to the Center for Biologics Evaluation and Research (CBER), Document Control Center (see addresses in § 600.2 of this chapter).

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, listings, other information, and updates, as applicable.

■ 41. In § 1271.25 revise paragraphs (a) introductory text and (a)(2) and (3), add paragraphs (a)(5) and (6), revise paragraph (c)(4), and add paragraph (d) to read as follows:

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration must include:

* * * * *

(2) Each physical location, including the street address, telephone number, email address, and the postal service ZIP code of the establishment;

(3) The name, address, telephone number, email address, and title of the reporting official;

* * * * *

(5) Each foreign establishment must also submit the name, address, telephone number, and email address of each importer that is known to the establishment, and the name of each person who imports or offers for import such HCT/P to the United States for purposes of importation; and

(6) Each foreign establishment must also submit the name, address, telephone number, and email address of its United States agent.

(i) The United States agent must reside or maintain a place of business in the United States.

(ii) Upon request from FDA, the United States agent must assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the Agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action is equivalent to providing the same information or documents to the foreign establishment.

(iii) The foreign establishment or the United States agent must report changes in the United States agent's name, address, telephone number, or email address to FDA within 30 calendar days of the change.

* * * * *

(c) * * *

(4) Any material change in any information previously submitted. Material changes include any change in registration and listing information, submitted, such as whether the HCT/P meets the criteria set out in § 1271.10.

(d) If your HCT/P is described under § 1271.20 and is regulated under a BLA, you must submit the information required under part 207 of this chapter using the procedures under subpart E of part 207.

■ 42. Revise § 1271.26 to read as follows:

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, or if there is a change in the United States agent's name, address, telephone number, or email address, you must submit an amendment to registration within 30 calendar days of the change.

Dated: August 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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Part IV

The President

Proclamation 9478—Papahānaumokuākea Marine National Monument Expansion

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Presidential Documents

Title 3—

The President

Proclamation 9478 of August 26, 2016

Papahānaumokuākea Marine National Monument Expansion

By the President of the United States of America

A Proclamation

Through Proclamation 8031 of June 15, 2006, as amended by Proclamation 8112 of February 28, 2007, the President established the Papahānaumokuākea Marine National Monument (Monument), to protect and preserve the marine area of the Northwestern Hawaiian Islands and the historic and scientific objects therein. As stated in Proclamation 8031, the area, including the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, the Midway Atoll National Wildlife Refuge, the Battle of Midway National Memorial, and the Hawaiian Islands National Wildlife Refuge, supports a dynamic reef ecosystem with more than 7,000 marine species, of which approximately one quarter are unique to the Hawaiian Islands. This diverse ecosystem is home to many species of coral, fish, birds, marine mammals, and other flora and fauna, including the endangered Hawaiian monk seal, the threatened green sea turtle, and the endangered leatherback and hawksbill sea turtles. In addition, this area has great cultural significance to the Native Hawaiian community and a connection to early Polynesian culture worthy of protection and understanding.

An area adjacent to the Monument, and that will constitute the Monument Expansion as set forth in this proclamation, includes the waters and submerged lands to the extent of the seaward limit of the United States Exclusive Economic Zone (U.S. EEZ) west of 163° West Longitude, and extending from the boundaries depicted on the map accompanying Proclamation 8031 as amended by Proclamation 8112 (adjacent area).

As required by the Antiquities Act, the adjacent area contains objects of historic and scientific interest that are situated upon lands owned or controlled by the Federal Government; they are geological and biological resources that are part of a highly pristine deep sea and open ocean ecosystem with unique biodiversity and that constitute a sacred cultural, physical, and spiritual place for the Native Hawaiian community.

This unique ecosystem has many significant features. Important geological features of the adjacent area include more than 75 seamounts, as well as a non-volcanic ridge that extends southwest towards the Johnston Atoll. Together, these features form biodiverse hotspots in the open ocean that provide habitat for deep-sea species, including sponges, other invertebrates, fish, and colonies of corals many thousands of years old. Recent science demonstrates that seamounts harbor a multitude of species with unique ecological traits, some newly discovered. Seamounts, ridges, and other undersea topographic features are important stepping stones that enable marine organisms to spread throughout the Hawaiian Archipelago, and between Hawaii and other archipelagoes. Undisturbed seamount communities in the adjacent area are of significant scientific interest because they provide opportunities to examine the impacts of physical, biological, and geological processes on ecosystem diversity, including understanding the impacts of climate change on these deep-sea communities. These seamounts and ridges also provide the opportunity for identification and discovery of many species not yet known to humans, with possible implications for research, medicine, and other important uses.

Recent scientific research, utilizing new technology, has shown that many species identified as objects in Proclamation 8031 inhabit previously unknown geographical ranges that span beyond the existing Monument, and in some cases the adjacent area also provides important foraging habitat for these species. For example, the endangered Hawaiian monk seal forages well beyond the existing Monument. Scientific research on Hawaiian monk seal foraging behavior has shown that monk seals may travel 80 miles and dive to depths of almost 2,000 feet while feeding.

Important bird species abound in the Monument and the adjacent area. Birds from the world's largest colonies of Laysan albatross, Black-footed albatross, and Bonin petrels, as well as significant populations of shearwaters, petrels, tropicbirds, the endangered Short-tailed albatross, and other seabird species forage in the adjacent area. We now know that albatrosses and Great Frigatebirds rely on the adjacent area during chick-brooding periods, when their foraging is focused within 200 miles of the nesting colonies on the Monument's islands and atolls. At other times, these wide-ranging species use a much broader range (over 1,600 miles) for foraging.

The adjacent area is a foraging and migration path for five species of protected sea turtles. While green and hawksbill turtles use the near-shore waters of the Monument for nesting, these species—along with the endangered leatherback turtle and threatened loggerhead and olive ridley turtles—migrate through the adjacent area to reach high-productivity foraging areas.

Twenty-four species of whales and dolphins have been sighted in the adjacent area. Three of these species are listed under the Endangered Species Act as threatened or endangered: sperm whales, fin whales, and sei whales. Cetacean use of the Monument Expansion varies; resident species such as spinner dolphins, false killer whales, and rough-toothed dolphins utilize the area year-round, whereas other species, such as humpback whales, use it as a wintering area. A wide variety of tropical and temperate water dolphin species inhabit the Monument Expansion, including pantropical spotted dolphins, spinner dolphins, striped dolphins, rough-toothed dolphins, and bottlenose dolphins. Several rarely sighted species of dolphin inhabit the area, including Risso's and Fraser's dolphins. Both of these species are primarily oceanic and found in waters deeper than 1,000 meters. Acoustic evidence also shows that endangered blue whales—the largest animals on Earth—visit the area and may migrate past the Hawaiian Islands twice a year.

Sharks, including tiger sharks and Galapagos sharks, are key species in the ecosystems of the Monument and adjacent area. These large and highly mobile predators have expansive home ranges and regularly move across the boundaries of the current Monument into the adjacent waters. Additionally, blue sharks, three species of thresher sharks, and two species of mako sharks inhabit the open ocean environment of the adjacent area.

The Monument and adjacent area are part of the most remote island archipelago on Earth. This biological and geographic isolation, coupled with unique oceanographic and geological conditions, has resulted in an ecosystem critical for new species formation and endemism. These forces result in some of the most unique and diverse ecological communities on the planet.

Importance to Native Hawaiian Culture

The ocean will always be seen as an integral part of cultural identity for the Native Hawaiian community. The deep sea, the ocean surface, the sky, and all the living things in the area adjacent to the Monument are important to this culture and are deeply rooted in creation and settlement stories. Native Hawaiian culture considers the Monument and the adjacent area a sacred place. This place contains the boundary between Ao, the world of light and the living, and Pō, the world of the gods and spirits from which all life is born and to which ancestors return after death. Long-distance voyaging and wayfinding is one of the most unique and valuable traditional practices that the Native Hawaiian community has developed and continues to advance. Once on the verge of cultural extinction, new double-hulled sailing canoes, beginning with the Hōkūleʻa in the 1970s, are bringing voyaging and wayfinding to new generations. This traditional practice relies on celestial, biological, and natural signs, such as winds, waves, currents and the presence of birds and marine life. The open ocean ecosystem and its natural resources in the adjacent area play an important role within the cultural voyaging seascape within the Hawaiian Archipelago.

Shipwrecks

World War II shipwrecks and aircraft in the adjacent area, though not identified as objects under the Antiquities Act in this proclamation, are of great historic interest. The naval portion of the Battle of Midway, one of the most important naval battles of World War II, occurred approximately 200 miles to the northeast of Midway Atoll, in the adjacent area. Deep-sea technologies have enabled the *USS Yorktown,* an aircraft carrier torpedoed during the battle, to be found at more than 16,000 feet below the ocean's surface. Eyewitness accounts and historical records tell the stories of the destroyer *USS Hammann,* five Japanese vessels (the four aircraft carriers *Hiryu, Soryu, Kaga,* and *Akagi,* and the cruiser *Mikuma*), and several hundred aircraft that were also lost during the battle in this area. The locations of these vessels have yet to be identified. All told, the adjacent area serves as a final resting place for the more than 3,000 people lost during the battle.

WHEREAS, the waters and submerged lands adjacent to the Monument (west of 163° West Longitude and seaward from the boundaries delineated in Proclamation 8031 as amended by Proclamation 8112 out to the limit of the U.S. EEZ) contain objects of historic and scientific interest that are situated upon lands owned or controlled by the Federal Government;

WHEREAS, section 320301 of title 54, United States Code (the "Antiquities Act"), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, it is in the public interest to preserve the marine environment, including the waters and submerged lands in the U.S. EEZ west of 163° West Longitude adjacent to Papahānaumokuākea Marine National Monument for the care and management of the historic and scientific objects therein;

WHEREAS, the well-being of the United States, the prosperity of its citizens and the protection of the ocean environment are complementary and reinforcing priorities; and the United States continues to act with due regard for the rights, freedoms, and lawful uses of the sea enjoyed by other nations under the law of the sea in managing the Papahānaumokuākea Marine National Monument and adjacent areas, and does not compromise the readiness, training, and global mobility of the U.S. Armed Forces when establishing marine protected areas;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be part of the Papahānaumokuākea Marine National Monument Expansion (Monument Expansion) and, for the purpose of protecting those objects, reserve as a part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map entitled "Papahānaumokuākea Marine National Monument Expansion" attached hereto, which forms a part of this proclamation. The Monument Expansion comprises the waters and submerged lands in the U.S. EEZ west of 163° West Longitude adjacent to the Monument. The Federal lands and interests in lands reserved consist of approximately 442,781 square miles, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of the Monument Expansion are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, leasing, or other disposition under the public land laws to the extent that those laws apply, including but not limited to, withdrawal from location, entry, and patent under mining laws, and from disposition under all laws relating to development of oil and gas, minerals, geothermal, or renewable energy. Lands and interest in lands within the Monument Expansion not owned or controlled by the United States shall be reserved as part of the Monument Expansion upon acquisition of title or control by the United States.

Management of the Marine National Monument

Nothing in this proclamation shall change the management of the Papahānaumokuākea Marine National Monument or any of the provisions specified in Proclamations 8031 and 8112. Terms used in this proclamation shall have the same meaning as those defined in Proclamation 8031. The Secretaries of Commerce and the Interior (Secretaries) shall share management responsibility for the Monument Expansion. The Secretary of Commerce, through the National Oceanic and Atmospheric Administration (NOAA), and in consultation with the Secretary of the Interior, shall have responsibility for management of activities and species within the Monument Expansion under the Magnuson-Stevens Fishery Conservation and Management Act, the Endangered Species Act (for species regulated by NOAA), the Marine Mammal Protection Act, and any other applicable Department of Commerce legal authorities. The Secretary of the Interior, through the United States Fish and Wildlife Service (FWS), and in consultation with the Secretary of Commerce, shall have responsibility for management of activities and species within the Monument Expansion under its applicable legal authorities, including the National Wildlife Refuge System Administration Act, the Refuge Recreation Act, and the Endangered Species Act (for species regulated by FWS), and Public Law 98–532 and Executive Order 6166 of June 10, 1933.

Additionally, the Secretary of Commerce should consider initiating the process under the National Marine Sanctuaries Act (16 U.S.C. 1431 *et seq.*) to designate the Monument Expansion area and the Monument seaward of the Hawaiian Islands National Wildlife Refuge and Midway Atoll National Wildlife Refuge and Battle of Midway National Memorial as a National Marine Sanctuary to supplement and complement existing authorities.

The Secretaries shall prepare a joint management plan, within their respective authorities and after consultation with the State of Hawaii, for the Monument Expansion within 3 years of the date of this proclamation, and shall promulgate as appropriate implementing regulations, within their respective authorities, that address any further specific actions necessary for the proper care and management of the objects and areas identified in this proclamation. The Secretaries shall revise and update the management plan as necessary. In developing and implementing any management plans and any management rules and regulations, the Secretaries shall consult, designate, and involve as cooperating agencies the agencies with jurisdiction or special expertise, including the Department of Defense and Department of State, in accordance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and its implementing regulations. If the Secretaries deem it beneficial, they may prepare a joint management plan for the entire Monument and Monument Expansion area, consistent with the provisions of the respective proclamations.

The Secretaries shall coordinate and work cooperatively with the Department of Defense, through the United States Navy, to protect, under the Sunken Military Craft Act, Public Law 108–375, 118 Stat. 1811, and any other applicable legal authorities, United States sunken military vessels and aircraft that are found within the geographic boundaries of the Monument Expansion. Any sunken craft of a foreign state found within the geographic boundaries of the Monument Expansion may be protected to the extent authorized under U.S. law, consistent with the President's Statement on United States Policy for the Protection of Sunken Warships (January 19, 2001).

This proclamation shall be applied in accordance with international law. The management plans and their implementing regulations shall impose no unlawful restrictions on innocent passage or otherwise unlawfully restrict navigation and overflight and other internationally recognized lawful uses of the sea in the Monument and Monument Expansion and shall incorporate the provisions of this proclamation regarding U.S. Armed Forces actions and compliance with international law. No restrictions shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law. Also, in accordance with international law, no restrictions shall apply to foreign warships, naval auxiliaries, and other vessels owned or operated by a state and used, for the time being, only on Government non-commercial service, in order to fully respect the sovereign immunity of such vessels under international law. The Secretary of State, in consultation with the Secretaries of Commerce and the Interior, shall take steps to protect the Monument Expansion as it does with respect to the Monument as specified in Proclamation 8031.

Restrictions

Prohibited Activities

The Secretaries shall prohibit persons from conducting or causing to be conducted the following activities:

1. Exploring for, developing, or producing oil, gas, or minerals, or any energy development activities within the Monument Expansion;

2. Using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a Monument Expansion resource;

3. Introducing or otherwise releasing an introduced species from within or into the Monument Expansion;

4. Removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging, or attempting to remove, move, take, harvest, possess, injure, disturb, or damage, any living or nonliving Monument Expansion resource, except as provided under regulated activities below;

5. Drilling into, dredging, or otherwise altering the submerged lands, or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands, except for scientific instruments;

6. Anchoring on or having a vessel anchored on any living or dead coral with an anchor, anchor chain, or anchor rope;

7. Deserting a vessel at anchor or adrift within the Monument Expansion; and

8. Commercial fishing and possessing commercial fishing gear except when stowed and not available for immediate use during passage without interruption through the Monument Expansion.

Regulated Activities

Subject to such terms and conditions as the Secretaries deem appropriate, the Secretaries may permit any of the following activities regulated by this proclamation if such activity is consistent with the care and management of the objects within the Monument Expansion and is not prohibited as defined above:

1. Native Hawaiian practices, including exercise of traditional, customary, cultural, subsistence, spiritual, and religious practices within the Monument Expansion;

2. Research and scientific exploration designed to further understanding of Monument Expansion resources and qualities;

3. Scientific research and development by Federal agencies that cannot be conducted in any other location;

4. Activities that will further the educational value of the Monument Expansion or will assist in the conservation and management of the Monument Expansion;

5. Anchoring scientific instruments; and

6. Non-commercial fishing, provided that the fish harvested, either in whole or in part, cannot enter commerce through sale, barter, or trade, and that the resource is managed sustainably.

Regulation of Scientific Exploration and Research

The prohibitions required by this proclamation shall not restrict scientific exploration or research activities by or for the Secretaries, and nothing in this proclamation shall be construed to require a permit or other authorization from the other Secretary for their respective scientific activities.

Emergencies and Law Enforcement Activities

The prohibitions required by this proclamation shall not apply to activities necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for law enforcement purposes.

U.S. Armed Forces Actions

1. The prohibitions required by this proclamation shall not apply to activities and exercises of the U.S. Armed Forces, including those carried out by the United States Coast Guard.

2. The U.S. Armed Forces shall ensure, by the adoption of appropriate measures not impairing operations or operation capabilities, that its vessels and aircraft act in a manner consistent, so far as is practicable, with this proclamation.

3. In the event of threatened or actual destruction of, loss of, or injury to a Monument Expansion resource or quality resulting from an incident, including but not limited to spills and groundings, caused by a component of the Department of Defense or the United States Coast Guard, the cognizant component shall promptly coordinate with the Secretaries for the purpose of taking appropriate action to respond to and mitigate any harm and, if possible, restore or replace the Monument resource or quality.

4. Nothing in this proclamation or any regulation implementing it shall limit or otherwise affect the U.S. Armed Forces discretion to use, maintain, improve, manage, or control any property under the administrative control of a Military Department or otherwise limit the availability of such property for military mission purposes, including, but not limited to, defensive areas and airspace reservations.

Other Provisions

Nothing in this proclamation shall be deemed to diminish or enlarge the jurisdiction of the State of Hawaii.

The Monument Expansion shall be the dominant reservation.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation.

Warning is hereby given to all unauthorized persons not to appropriate, excavate, injure, destroy, or remove any feature of this Monument Expansion and not to locate or settle upon any lands thereof.

This proclamation is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of August, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

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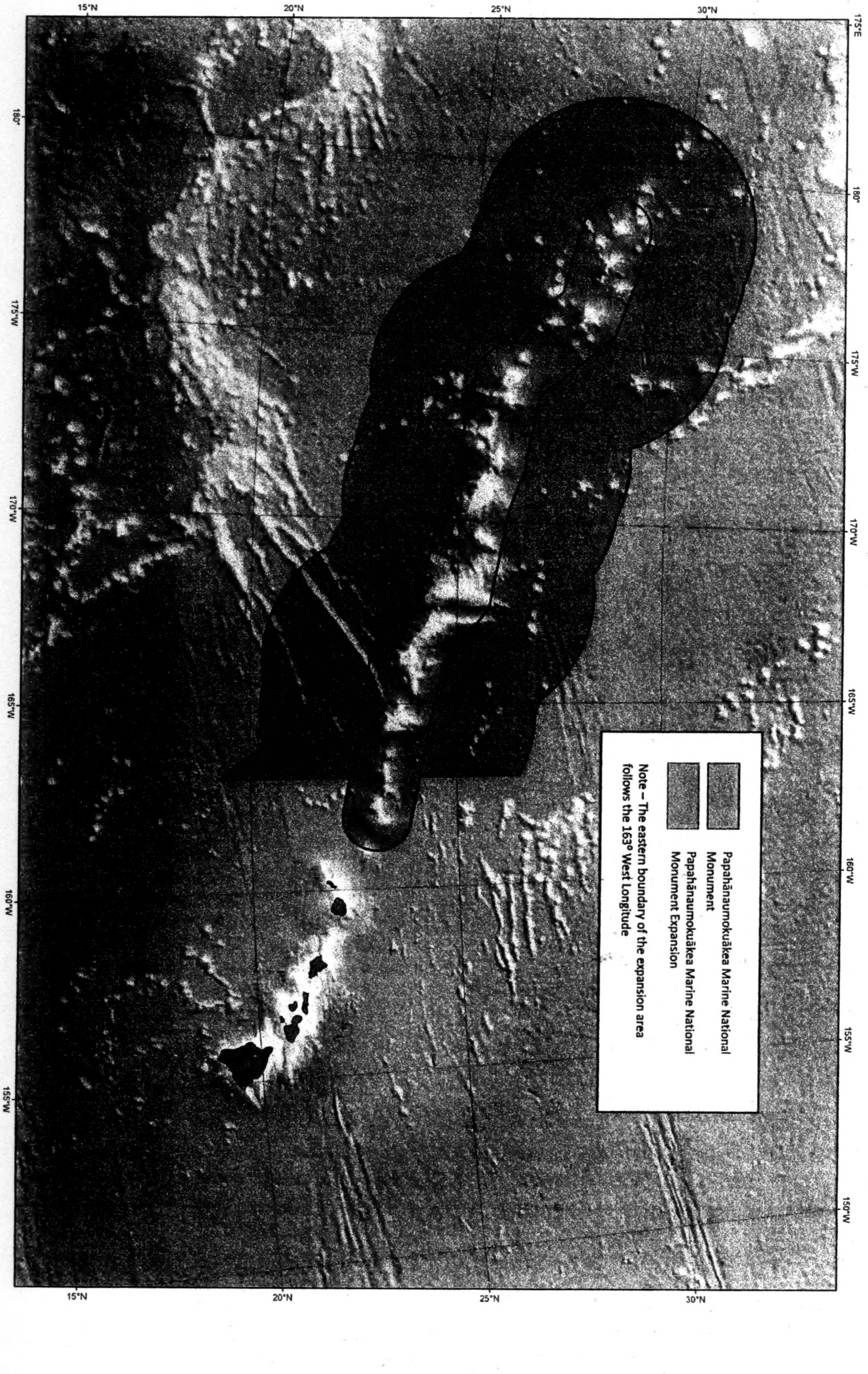
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Papahānaumokuākea Marine National Monument
Papahānaumokuākea Marine National Monument Expansion
Note – The eastern boundary of the expansion area follows the 163° West Longitude

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